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Food and Drug Administration

Classification of Obstetrical and Gynecological Devices

Development of General Provisions; Proposed Rules

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 884]

Classification of Obstetrical and Gynecological Devices: Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The agency is proposing general rules applicable to the classification of all obstetrical and gynecological devices. The Medical Device Amendments of 1976 require the Food and Drug Administration (FDA) to classify all medical devices intended for human use into three categories: Class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulations classifying individual obstetrical and gynecological devices, which are being published elsewhere in this issue of the **Federal Register.** The preamble also describes the activities of the Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee that makes recommendations to FDA concerning the classification of obstetrical and gynecological devices.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Durg Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Lillian L. Yin, Bureau of Medical Devices (HFK– 470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: Class I, general controls; class II, performance standards; class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), the Commissioner issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848).

Activities of Panel

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Obstetrical and Gynecological Device Classification Panel (the Panel) was originally chartered on April 16, 1973, as the Panel on Review of Obstetric and Gynecologic Devices. The FDA placed a report of the Panel's tentative classification recommendations on file with the office of the Hearing Clerk (HFA–305), Food and Drug Administration, and announced the availability of the report to the public by notice published in the **Federal Register** of December 30, 1975 (40 FR 59769).

On August 9, 1976, the Panel and other preamendments device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA had referred to it to make certian that its recommendations were in accord with the amendments.

Throughout the Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of obstertrical and gynecological devices. The Panel also invited experts to testify and sought information on many devices from the published literature.

In October 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and former Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, and announced its availability to the public by notice published in the **Federal Register** of November 29, 1977 (42 FR 60792). At a meeting held on May 8, 1978, the Panel changed its previous recommendations concerning the classification of several devices. The summary of minutes of this meeting shows these changes and has been placed in the office of the Hearing Clerk, Food and Drug Administration. Also available in the office of the Hearing Clerk are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual obstetrical and gynecological device proposed classification regulations. Interested persons may review these documents in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday and Friday.

List of Obstetrical and Gynecological Devices

In 1972, FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of obstetrical and gynecological devices. The Panel supplemented the list utilizing its members' knowledge of obstetrical and gynecological devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included.

The Commissioner is proposing to establish a new Part 884 in Title 21 of the Code of Federal Regulations. Part 884 will consist of sections that identify each obstetrical and gynecological device, give a brief narrative description of the device, and state the classification of that device. A list of the obstetrical and gynecological devices appears elsewhere in this preamble.

Individual Obstetrical and Gynecological Device Classification Regulations

Elsewhere is this issue of the **Federal Register**, the Commissioner is issuing 69 individual proposed regulations to classify each obstetrical and gynecological device. The Commissioner is proposing to classify 5 obstetrical and gynecological devices into class I (general controls), 48 obstetrical and gynecological devices into class II (performance standards), and 16 obstetrical and gynecological devices into class III (premarket approval). The Commissioner also is publishing the recommendations of the Panel regarding these devices, as required by section 513(c)(2) and (d)(1) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

Published Panel Recommendation

Each published Panel recommendation concerning an obstetrical and gynecological device inclused the information described below.

1. *Identification.* Both the Panel recommendation and proposed FDA classification regulation include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 884.1 (21 CFR 884.1), manufacturers who submit premarket notification submissions under section 510(k) of the act and Part 807 of the regulations cannot show merely that a newly offered device is accurately described by the section title and identification provisions of a classification regulation. Although a new device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendments device (or to a postamendments device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The Commissioner believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes that the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls), class II (performance standards), or class III (premarket approval).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). The Panel recommended that none of the obstetrical and gynecological devices that are recommended for classification into class I be exempted from requirements under these sections. Manufacturers and other interested persons may submit comments on the appropriateness of exempting manufacturers of particular class I devices from one or more of the requirements under sections 510, 519, and 520(f) of the act. These comments should be supported by data and views showing that the application of these requirements to manufacturers of a device is not necessary to assure that the device is safe and effective and in compliance with the act, and that, despite the exemption, FDA will be able to discharge its regulatory responsibilities under the act.

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high" or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority ("high" or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and III Devices," the Commissioner is not, however, proposing the establishment of agency priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, the Commissioner is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The summary of reasons for a recommendation identifies any device that is an implant or a life-supporting or life-sustaining device. The summary of reasons for any implant or life-supporting or life-sustaining device that is not recommended for classification into class III also explains why the Panel determined that classification of the device into class III is not necessary to provide reasonable assurance of its safety and effectiveness. The agency provides a similar explanation in the "Proposed Classification" section of the preamble to any proposal to classify an implant or a life-supporting or life-sustaining device into a class other than class III.

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on Panel member's personal knowledge of, and familiarity with, the devices under review. The Panel particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear that the term "data" has a special meaning in section 513(a)(2) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in this section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts (House Committee

on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rept. 94853, 94th Congress, 2d Session 40 (1976)). The Commissioner has determined that clinical experience and judgment is valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the "Proposed Classification" section of the preambles to individual obstetrical and gynecological device regulations. The Commissioner is adopting, as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by obstetrical and gynecological devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the individual device. In some cases, FDA has identified additional risks to health presented by a device. These additional risks are set out in the section of the preamble concerning the "Proposed Classification" of a particular device.

Because the classification recommendations and FDA regulations do not identify all risks to health presented by obstetrical and gynecological devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each proposed regulation to classify an obstetrical and gynecological device states whether FDA agrees with the Panel's recommendation, describes the agency's proposed classification of the device, and proposes a new section in Part 884 in which the device classification will be codified.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Priorities for Class II and Class III Devices

For a device that the Panel recommends be classified into class II or class III, section 513(c)(2)(A) of the act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of priorities for application to the device of performance standards or premarket approval requirements. In developing its advice concerning priorities ("high" or "low") of devices recommended for classification into class II or class III, the Panel compared the device with other obstetrical and gynecological devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panel recommended assignment of a "high priority" only to those class II or class III devices that the Panel believed should receive the agency's immediate attention.

The Commissioner is not proposing at this time to establish priorities for development of performance standards for class II devices or application of premarket approval requirements to class III devices. Section 513(d)(3) of the act authorizes, but does not require establishment of these priorities. At a later date, however, the Commissioner will establish priorities for the development of standards for class II devices and the application of premarket approval requirements to class III devices. These priorities will be based on the classification panels' recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

The agency intends to proceed as quickly as the statute and classification panel resources permit to require premarket approval of devices classified into class III. There are two factors affecting the length of time necessary before FDA requires submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: The number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a classification panel. For example, where FDA classifies into class III only a few devices within a Panel's specialty area, FDA may at the same time also publish regulations under section 515(b) of the act requiring premarket approval for many of the class III devices considered by the Panel, regardless of whether of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification, during which a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

List of Obstetrical and Gynecological Devices

The following is a list of the obstetrical and gynecological devices FDA is proposing to classify, the section in the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Subpart B—Obstetrical and Gynecological Diagnostic Devices

Section	Device	Docket No.	Class
884.1050	Endocervical aspirator	78N-1107	II
884.1060	Endometrial aspirator	78N-1108	III
884.1100	Endometrial brush	78N-1109	III
884.1175	Endometrial suction curette and accessories	78N-1110	II
884.1185	Endometrial washer	78N-1111	III
884.1300	Uterotubal carbon dioxide insufflator and accessories	78N-1112	II
884.1425	Perineometer	78N-1113	II
884.1550	Amniotic fluid sampler (amniocentesis tray)	78N-1114	II
884.1560	Fetal blood sampler	78N-1115	II
884.1600	Transabdominal amnioscope (fetoscope) and accessories	78N-1116	III
884.1630	Colposcope	78N-1117	II
884.1640	Culdoscope and accessories	78N-1118	II
884.1660	Transcervical endoscope (amnioscope) and accessories	78N-1119	II
884.1690	Hysteroscope and accessories	78N-1120	II
884.1700	Hysteroscopic insufflator	78N-1121	II
884.1720	Gynecologic laparoscope and accessories	78N-1122	II
884.1730	Laparoscopic insufflator	78N-1123	II

Subpart C—Obstetrical and Gynecological Monitoring Devices

884.2050	Obstetric data analyzer	78N-1124	III
884.2225	Obstetric-gynecologic ultrasonic imager	78N-1125	II
884.2600	Fetal cardiac monitor	78N-1126	II
884.2620	Fetal electroencephalographic monitor	78N-1127	III
884.2640	Fetal phonocardiographic monitor and accessories	78N-1128	II
884.2660	Fetal ultrasonic monitor and accessories	78N-1129	II
884.2675	Fetal scalp circular (spiral) electrode and applicator	78N-1130	II
884.2685	Fetal scalp clip electrode and applicator	78N-1131	III
884.2700	Intrauterine pressure monitor and accessories	78N-1132	II
884.2720	External uterine contraction monitor and accessories	78N-1133	II
884.2740	Perinatal monitoring system and accessories	78N-1134	II
884.2900	Fetal stethoscope	78N-1135	I
884.2960	Obstetric ultrasonic transducer and accessories	78N-1136	II

Subpart D—Obstetrical and Gynecological Prosthetic Devices

884.3200	Cervical drain	78N-1137	II
884.3575	Vaginal pessary	78N-1138	II
884.3650	Fallopian tube prosthesis	78N-1140	II
884.3900	Vaginal stent	78N-1141	II

Subpart E—Obstetrical and Gynecological Surgical Devices

884.4100	Endoscopic electrocautery and accessories	78N-1142	III
884.4120	Gynecologic electrocautery and accessories	78N-1143	II
884.4150	Bipolar endoscopic coagulator-cutter and accessories	78N-1144	III
884.4160	Unipolar endoscopic coagulator-cutter and accessories	78N-1145	II
884.4250	Expandable cervical dilator	78N-1146	III
884.4260	Hygroscopic-larminaria cervical dilator	78N-1147	II
884.4270	Vibratory cervical dilator	78N-1148	III
884.4340	Fetal vacuum extractor	78N-1149	II
884.4400	Ostetric forceps	78N-1150	II
884.4500	Obstetric fetal destructive instrument	78N-1151	II
884.4520	Obstetric-gynecologic general manual instrument	78N-1152	I
884.4530	Obstetric-gynecologic specialized manual instrument	78N-1153	II
884.4550	Gynecologic surgical laser	78N-1154	II
884.4900	Obstetric table and accessories	78N-1155	II

Subpart F—Obstetrical and Gynecological Therapeutic Devices

884.5050	Metreurynter-balloon abortion system	78N-1156	III
884.5070	Vacuum abortion system	78N-1157	II
884.5100	Obstetric anesthesia set	78N-1158	II
884.5150	Nonpowered breast pump	78N-1159	I
884.5160	Powered breast pump	78N-1160	II
884.5250	Cervical cap	78N-1161	II
884.5225	Abdominal decompression chamber	78N-1162	II
884.5300	Condom	78N-1163	II
884.5350	Contraceptive diaphragm and accessories	78N-1164	II
884.5360	Contraceptive intrauterine device (IUD) and introducer	78N-1165	III
884.5380	Contraceptive tubal occulusion device (TOD) and introducer	78N-1166	III
884.5390	Perineal heater	78N-1167	II
884.5400	Menstrual cup	78N-1168	II
884.5425	Scented deodorized menstrual pad	78N-1169	II
884.5435	Untreated menstrual pad	78N-1170	I
884.5460	Scented deodorized menstrual tampon	78N-1171	II
884.5470	Untreated menstrual tampon	78N-1172	II
884.5900	Vaginal douche kit	78N-1173	II
884.5920	Vaginal insufflator	78N-1174	I
884.5940	Powered vaginal muscle stimulator	78N-1175	III
884.5960	Genital vibrator	78N-1176	II

Devices Considered by Two or More Panels

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's recommendations and a single proposed classification regulation. The following devices were considered by the Obstetrical and Gynecological Device Classification Panel and by other panels:

1. The General Hospital Device Classification Panel recommended that the prophylactic (condom) be classified into class II. The Obstetrical and Gynecological Device Classification Panel recommended that the contraceptive condom (rubber) be classified into class II. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying the condom into class II, and is publishing the two panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

2. The Obstetrical and Gynecological Device Classification Panel and the other panels listed below made classification recommendations concerning the following devices:

Device and Other panel(s)

Cervical Cryosurgery and accessories, General and plastic surgery
Manual sitz bath, Physical medicine
Ob-Gyn abdominal binder, General hospital
Breast binder, General hospital
Nipple shield, General hospital

The Commissioner is not at this time publishing the Obstetrical and Gynecological Device Classification Panel's recommendations to classify the devices listed above. The Commissioner will publish these recommendations, and proposed classification regulations, when he publishes the recommendations of other panels that reviewed the devices.

Cerclage Suture Prosthesis

At a future date, FDA will publish in the **Federal Register** a final regulation stating that one obstetrical and gynecological device (cerclage suture prosthesis) is classified into class III (premarket approval) because of transitional provisions of the act in section 520(1) (21 U.S.C. 360j(1)). The transitional provisions classify into class III any device previously regarded by FDA as a new drug. At the time FDA publishes this regulation, the agency also will publish the Panel's recommendations regarding the cerclage suture prosthesis.

Environmental Impact

The Commissioner has carefully considered the environmental effects of proposed § 884.1 and of the proposed obstetrical and gynecological device classification regulations and because the proposed actions will not significantly affect the quality of the human environment has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration (address above)

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)), and under authority delegated to the Commissioner (21 U.S.C. 5.1), the Commissioner proposes that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 884 and Subpart A, to read as follows:

PART 884—OBSTETRICAN AND GYNECOLOGICAL DEVICES

Subpart A—General Provisions

Sec.
884.1 Scope.
Authority: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c and 701(a)).

Subpart A—General Provisions

§ 884.1 Scope.

(a) This part sets forth the classification of obstetrical and gynecological devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 of this chapter cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

(c) To avoid duplicative listings, and obstetrical or gynecological device that has two or more types of uses (e.g., use both as a diagnostic device and as a therapeutic device) is listed in the subpart representing one use of the device, rather than in two or more subparts.

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding proposed § 884.1. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office, between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1106]

[FR Doc. 79–9410 Filed 4–2–79; 8:45 am]
BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Endocervical Aspirators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endocervical aspirators into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of endocervical aspirators:

1. Identification: An endocervical aspirator is a device designed to remove tissue from the endocervix (mucous membrane lining the canal of the cervix of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to evaluate the endocervical tissue to detect malignant and premalignant lesions.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that endocervical aspirators be classified into class II (performance standards) because the Panel believes that the device materials contacting the endocervical tissues should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel recommends that the method of sterilization to prevent infection be stated in the device labeling. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel states that because endocervical cancer appears on the surface of the endocervix, a sample of the cells of the endocervical tissue can be adequately removed with this device. The endocervical aspirator may not be as effective as biopsy in the detection of lesions on the lower cervix, or as curettage for lesions of the upper cervix, but the Panel believes that proper use of the device can achieve adequate results. The Panel believes, however, that the use of this device should not replace biopsy or curettage in cases of suspected malignancy. The Panel also recommends that this device not be used when the patient is pregnant. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device.

5. Risks to health: (a) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient. (b) Misdiagnosis: Inadequate design could lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that endocervical aspirators be classified into class II (performance standards). The Commissioner believes that a performance standard is

necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 by adding new Subpart B and new § 884.1050 as follows:

Subpart B—Obstetrical and Gynecological Diagnostic Devices

§ 884.1050 Endocervical aspirator.

(a) *Identification.* An endocervical aspirator is a device designed to remove tissue from the endocervix (mucous membrane lining the canal of the cervix of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to evaluate and endocervical tissue to detect malignant and premalignant lesions.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1107]

[FR Doc. 79–9411 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M]

[21 CFR Part 884]

Classification of Endometrial Aspirators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endometrial aspirators into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of endometrial aspirators:

1. Identification: An endometrial aspirator is a device used to remove materials from the endometrium (the mucosal lining of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to study endometrial cytology (cells).

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that endometrial aspirators be classifed into class III (premarket approval) because the Panel believes that satisfactory performance has never been demonstrated. The Panel believes, however, that certain characteristics of this device could be controlled by performance standards. The device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The method of sterilization must be stated in the device labeling to prevent infection. The Panel also notes that this device should not be used when the patient is pregnant. Because this device may not be as effective as endometrial biopsy for routine screening of patients, the Panel believes that its use should not replace dilation and currettage for the diagnosis of cases of abnormal bleeding or suspected malignancy. The extent to which the endometrial aspirator takes representative samples is vital in the diagnosis of malignant and premalignant endometrial lesions. Because endometrial malignant and premalignant lesions sometimes develop deep within the endometrial tissue, a sample of the cells of the endometrial surface may not be adequate for an accurate diagnosis. If the device design does not permit effective sampling of uterine mucosa, there exists the risk of misdiagnosis of cancer. The Panel believes that a performance standard alone will not provide reasonable assurance of the safety and effectiveness of the device and that there is insufficient information to establish a standard to provide such assurance. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel also reviewed the current literature, citing an article which indicates that the endometrial aspirator fails to detect 25 to 50 percent of malignancies and 50 to 75 percent of premalignant lesions (Ref. 1).

5. Risks to health: (a) Misdiagnosis: Inadequate design could lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that would cause infection. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that endometrial aspirators be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and has obtained additional data and information describing the application of endometrial sampling devices which do not involve curettage that are used to detect malignant and premalignant lesions of the uterus. The literature shows that the endometrial aspirator failed to detect malignant lesions or premalignant lesions satisfactorily (Ref. 2). The Commissioner also reviewed this device in its intended use for menstrual

extraction (5 to 20 days following the failure of an expected menstruation) (Ref. 3). For this indication, the device failed to evacuate completely the pregnant uterus in 12.1 percent of cases, whereupon a second procedure was required to complete the abortion (Ref. 4).

The Commissioner believes that the device is purported or represented to be for a use (removal of cells to study endometrial cytology for cancer screening) that is of substantial importance in preventing impairment of human health. The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient if practitioners rely upon the information derived from this device to diagnose malignant or premalignant lesions. The Commissioner believes that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and that insufficient information exists to establish a performance standard that will provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Anderson, D. G., et al., "The Cytologic Diagnosis of Endometrial Adenocarcinoma," *American Journal of Obstetrics and Gynecology*, 125(3):376, June 1976.

2. Isaacs, J. H. and R. W. Wilhoite, "Aspriation Cytology of the Endometrium: Office and Hospital Sampling Procedures," *American Journal of Obstetrics and Gynecology*, 118(5):679, March 1974.

3. Landesman, R., et al., "Menstrual Extraction: Review of 400 Procedures at the Women's Services, New York, New York," *Contraception*, 8(6):527, December 1973.

4. Bendel, R., et al., "Endometrial Aspriation in Fertility Control," *American Journal of Obstetrics and Gynecology*, 125(3):328, June 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1060 as follows:

§ 884.1060 Endometrial aspirator.

(a) *Identification.* An endometrial aspirator is a device designed to remove materials from the endometrium (the mucosal lining of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to study endometrial cytology (cells).

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1108]

[FR Doc. 79–9412 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Endometrial Brushes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endometrial brushes into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of endometrial brushes:

1. Identification: An endometrial brush is a device designed to remove samples of the endometrium (the mucosal lining of the uterus) by brushing its surface. This device is used to study endometrial cytology (cells).

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that endometrial brushes be classified into class III (premarket approval) because the Panel believes that satisfactory performance has never been demonstrated. The Panel, however, believes that certain characteristics of this device could be controlled by performance standards. The device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. Material and design standards are necessary to prevent the bristles of the brush from shedding and causing irritation and damage to tissue. The Panel believes that the method of sterilization to prevent infection should be stated in the labeling. The Panel also notes that this device should not be used when the patient is pregnant. Because this device may not be as effective as endometrial biopsy for routine screening of patients, the Panel believes that its use should not replace dilation and curettage for the diagnosis of cases of abnormal bleeding or suspected malignancy. The extent to which the endometrial brush takes representative samples is vital in the diagnosis of malignant and premalignant endometrial lesions. Because endometrial malignant and premalignant lesions sometimes develop deep within the endometrial tissue, a sample of only the cells of the endometrial surface may not be adequate for an accurate diagnosis. If the device design does not permit effective sampling of uterine mucosa, the risk of misdiagnosing cancer may exist. The Panel believes that a performance standard alone will not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a standard to provide such assurance. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory

performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel also reviewed the current literature, citing one article which indicates that the endometrial brush fails to detect malignant lesions in 36 percent of the reported cases and fails to collect an adequate sample for diagnosis in 32 percent of the cases (Ref. 1).

5. Riskes to health: (a) Misdiagnosis: Inadequate design could lead to the generation of inaccurate diagnositc data. If inaccurate diagnositic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient. (d) Irritation and trauma: The shedding of the bristles of this device could result in irritation and damage to tissue.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that endometrial brushes be classified into class III (premarket approval). The Commissioner believes that the device is purported or represented to be for a use (removal of cells to study endometrial cytology for cancer screening) that is of substantial importance in preventing impairment of human health. The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient if practitioners rely upon the information derived from this device to diagnose malignant or premalignant lesions. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m. Monday through Friday.

1. Anderson, D. G. et al., "The Cytologic Diagnosis of Endometrial Adenocarcinoma," *American Journal of Obstetrics and Gynecology*, 125(3):276, June 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1100 as follows:

§ 884.1100 Endometrial brush.

(a) *Identification.* An endometrial brush is a device designed to remove samples of the endometrium (the mucosal lining of the uterus) by brushing its surface. This device is used to study endometrial cytology (cells).

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1109]

[FR Doc. 79–9413 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Endometrial Suction Curettes and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endometrial suction curettes and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of endometrial suction curettes and accessories:

1. Identification: An endometrial suction curette is a device designed to remove material from the mucosal lining of the uterus by scraping and vacuum suction. This device is used for biopsy or menstrual extraction. This generic type of device may include catheters, syringes, and tissue filters or traps. The Panel previously considered this generic type of device under the name "edometrial suction biopsy curette."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that endometrial suction curettes and accessories be classified into class II (performance standards) because the Panel believes that device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel recommends that the method of sterilization to prevent infection be stated in the device labeling. The Panel also believes that material standards are necessary to assure appropriate flexibility of the device to prevent perforation of the uterus. The Panel states that a design standard is necessary to control the serration of the curette end, which could cause trauma to the uterine tissues. The Panel also notes that when the device is used with other devices as a system, the combination must be compatible. The Panel recommends that when this device is used with a powered vacuum source, the vacuum pressure must be controlled so that it is not excessive. This device should not be used for biopsy when the patient is pregnant; the Panel states that the suction curette can scrape deep into the endometrial tissue when taking a representative sample of the tissue. Even though this device is effective for routine screening of cancer when used

properly, the Panel recommends that it not replace dilation and curettage for diagnosing cases of abnormal bleeding or suspected malignancy. The Panel beieves that general controls alone will not provide sufficient control over the characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommedation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. A review of gynecological textbooks and handbooks of procedure shows many years of extensive clinical experience with and widespread use of this device.

5. Risks to health: (a) Trauma: An improperly serrated curette tip could cause injury to the endometrium. (b) Perforation: A curette that is too rigid will increase the risk of uterine perforation. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient. (d) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that endometrial suction curettes and accessories be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation and has obtained additional information and data describing endometrial suction curettes. Publishes studies of large-scale use demonstrate the suction curette to be a cost-effective device with minimal risks (Refs. 1, 2, and 3). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Chiasson, S. W., P. Huang, and S. P. Regec, "Suction Curettage of the Endometrium in an Ambulatory Patient," *Journal of Reproductive Medicine*, 21(3):159–162, September 1978.

2. Webb, M. J. and T. A. Gaffey, "Outpatient Diagnostic Aspiration Curettage," *Obstetrics and Gynecology*, 47(2):239–242, February 1976.

3. van der Vlugt, T. and P. T. Piotrow, "Menstrual Regulation Update," Population Report, Series F, No. 4, May 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1175 as follows:

§ 884.1175 Endometrial suction curette and accessories.

(a) *Identification.* An endometrial suction curette is a device designed to remove material from the mucosal lining of the uterus by scraping and vacuum suction. This device is used for biopsy or menstrual extraction. This generic type of device may include catheters, syringes, and tissue filters or traps.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1110]

[FR Doc. 79–9414 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Endometrial Washers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endometrial washers into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of endometrial washers:

1. Identification: An endometrial washer is a device used to remove materials from the endometrium (the mucosal lining of the uterus) by washing with water or saline solution under negative pressure. This device is used to study endometrial cytology (cells).

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that endometrial washers be classified into class III (premarket approval) because the Panel believes that satisfactory performance has never been demonstrated. The Panel, however, believes that certain characteristics of this device could be controlled by performance standards. The device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. When using this device, intrauterine pressure should not exceed 50 millimeters of mercury (mmHg). Design standards are necessary to prevent excessive pressure or vacuum that could cause tissue trauma or infection. The Panel recommends that the method of sterilization

be stated in the device labeling. Material standards would ensure the appropriate flexibility of the endometrial washer to prevent uterine perforation. The Panel also notes that this device should not be used when the patient is pregnant. Because this device may not be as effective as endometrial biopsy for screening of patients, the Panel believes that its use should not replace dilation and curettage for diagnosing abnormal bleeding or suspected malignancy. The extent to which the endometrial washer takes representative endometrial samples is vital in the diagnosis of malignant and premalignant endometrial lesions. Because endometrial malignant and premalignant lesions sometimes occur deep within the endometrial tissue, a sample only of the cells of the endometrial surface is not adequate for an accurate diagnosis. If the device's design does not permit effective sampling of uterine mucosa, the risk of misdiagnosing cancer exists. The Panel believes that a performance standard alone will not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a standard. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel also reviewed the current literature. In one case study of 220 patients, the device failed to detect 6 of 12 cases of adenocarcinoma (cancer) (Ref. 1). In another case study of 556 patients, the device failed to detect 14 of 25 cases of adenocarcinoma (Ref. 2). Many of the failures were due to inadequate specimens.

5. Risks to health: (a) Misdiagnosis: Inadequate design could lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes into contact with the patient. (d) Perforation: Rigidity of the device could result in a part of the device puncturing the patient's uterus. (e) Trauma: Excessive vacuum in the divice could result in tissue damage if the device does not have fail-safe means to control the vacuum.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that endometrial washers be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and has obtained additional information and data describing endometrial sampling devices that do not involve curettage and that are used to detect malignant and premalignant lesions of the uterus. Although early studies showed that the device may be effective, more recent comparative studies have shown the need for more data (Refs. 3 and 4).

The Commissioner believes that the devices is purported or represented to be for a use (removal of cells to study endometrial cytology for cancer screening) that is of substantial importance in preventing impairment of human health. The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient if practitioners rely upon the information derived from this device to diagnose malignant or premalignant lesions. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to profide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Afonso, J. F., "Value of the Gravlee Jet Washer in the Diagnosis of Endometrial Cancer," *Obstetrics and Gynecology*, 46(2):141–146, August 1975.

2. Twiggs, L. B., et al., "Gravlee Jet Irrigator: Efficacy in Diagnosis of Endometrial Neoplasia," *Journal of the American Medical Association*, 235(25):2748–2750, June 1976.

3. Abate, S. D., et al., "A Comparative Study of the Endometrial Jet-Washing Technic and Endometrial Biopsy," *American Journal of Clinical Pathology*, 58:118–122, August 1972.

4. Anderson, D. G. et at., "The Cytologic Diagnosis of Endometrial Adenocarcinoma," *American Journal of Obstetrics and Gynecology*, 125(3):276, June 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701ca), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1185 as follows:

§ 884.1185 Endometrial washer.

(a) *Identification.* An endometrial washer is a device used to remove materials from the endometruim (the mucosal lining of the uterus) by washing with water or saline solution under negative pressure. This device is used to study endometrial cytology (cells).

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979. submit to the Hearing Clerk (HFT–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1111]

[FR Doc. 79–9415 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Uterotubal Carbon Dioxide Insufflators and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying uterotubal carbon dioxide insufflators and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of uterotubal carbon dioxide insufflators and accessories:

1. Identification: A uterotubal carbon dioxide insufflator is a device used to test the patency (lack of obstruction) of the fallopian tubes by pressurizing the uterus and fallopian tubes and filling them with carbon dioxide gas.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that uterotubal carbon dioxide insufflators and accessories be classified into class II (performance standards) because the Panel believes that materials contacting the body should meet a biocompatibility standard to prevent adverse tissue reaction. Also, the Panel states that electrical safety standards are required to minimize the hazard of electrical shock. The Panel believes that a design standard is necessary to assure safe pressure levels. Excessive pressure from the insufflator could casue damage to internal organs and the induction of emboli into the blood stream. To control the pressure of the device, the Panel recommends that the device incorporate fail-safe means to preclude the possibility of excessive pressure. The Panel also believes that uterotubal carbon dioxide insufflators must meet certain measurement standards by addressing the accuracy and resolution of controls, and indicators for flow rate, pressure, and volume, to minimize further the possibility of overinsufflation. The Panel also recommends that the only gas used be carbon dioxide. This device must not be used in pregnancy, during menstruation, or after ovulation. The Panel states that when this device is used with other devices as a system, the combination must be compatible. The Panel also recommends that, to prevent infection, the method of sterilization be stated in the device labeling. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The diagnostic procedure during which this device is used is described is standard obstetrical and gynecological textbooks. The procedure is a common fertility test (Rubin test), whereby the uterus is insufflated and the patency of the fallopian tubes is determined by the uterine pressure level reached at a specified gas flow rate (Ref. 1).

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Trauma and hemorrhage: Failure of a control mechanism of the device could result in a part of the device injuring the patient. (d) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient. (e) Uterine rupture and gas emboli: Excessive pressure of the device could result in uterine rupture or gas emboli if controls and indicators for flow rate are not accurate.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that uterotubal carbon dioxide insufflators and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Greenhill, J. P., "Office Gynecology," 9th Ed., Yearbook Publishers, Inc., Chicago, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1300 as follows:

§ 884.1300 Uterotubal carbon dioxide insufflator and accessories.

(a) *Identification.* A uterotubal carbon dioxide insufflator is a device used to test the patency (lack of obstruction) of the fallopian tubes by pressurizing the uterus and fallopian tubes and filling them with carbon dioxide gas.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1112]

[FR Doc. 79–9416 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Perineometers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying perineometers into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of perineometers:

1. Identification: A perineometer is an intravaginal fluid-filled sack, attached to an external manometer, used to measure the strength of the perineal muscles by offering resistance to a patient's voluntary contractions of these muscles. This device is used to diagnose and to correct urinary incontinence or sexual dysfunction through exercise.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that perineometers be classified into class II (performance standards) because the Panel believes that the device materials contacting vaginal tissue should meet a biocompatibility standard to prevent an adverse tissue reaction. The sack portion of the perineometer, often made of rubber, is difficult to clean and sterilize; therefore, the Panel recommends that the method of sterilization be stated in the device labeling to prevent infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also recommends that the device be used only under the management of a physician. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel notes that in a study of 500 cases of mild-to-moderate stress incontinence, 75 percent of the patients obtained complete relief in 6 to 8 weeks with no untoward effects (Ref. 1).

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorgainisms that could cause infection. (b) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that perineometers be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Kegel, A., "Physiologic Therapy for Urinary Stress Incontinence," *Journal of the American Medical Association*, 146:915, 1951.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1425 as follows:

§ 884.1425 Perineometer.

(a) *Identification.* A perineometer is an intravaginal fluid-filled sack, attached to an external manometer, used to measure the strength of the perineal muscles by offering resistance to a patient's voluntary contractions of these muscles. This device is used to diagnose and to correct urinary incontinence or sexual dysfunction through exercise.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1113]

[FR Doc. 79–9417 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Amniotic Fluid Samplers (Amniocentesis Trays)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying amniotic fluid samplers (amniocentesis trays) into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gyncological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. the Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of amniotic fluid samplers (amniocentesis trays):

1. Identification: An amniotic fluid sampler is a device used for amniocentesis (transabdominal aspiration of fluid from the amniotic sac). The sampler consists of disposable instruments, drapes, specimen containers, and other accessories on a tray. The Panel previously considered this generic type of device under the name "amniocentesis tray."

2. Recommended classification: Class II (performance standards). The Panel

recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that amniotic fluid samplers (amniocentesis trays) be classified into class II (performance standards) because the Panel believes that material standards are necessary to assure an adequate surface finish and appropriate tensile strength to prevent trauma and mortal injury to the fetus. The Panel states that the device materials contacting the body should meet a biocompatibility standard to prevent adverse tissue reaction. The Panel recommends that, to prevent infection, the method of sterilization should be stated in the device labeling. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel states that only a physician should use the device for amniocentesis. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. Panel member J. T. Queenan, M.D., performed over 5,000 procedures and attested to the safety of the procedure if done with care (Ref. 1). The Panel also reviewed the literature on the research completed by the National Institute of Child Health and Human Development. This study determined that amniocentesis is a highly accurate and safe procedure (Ref. 2).

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

(b) Trauma: Breakage or roughness of the needle could result in mortal injury to the fetus. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient or fetus. (d) Fetal immunizations: Fetal immunization (incompatibility of the blood of the mother and fetus) can be minimized by the use of preoperative diagnostic ultrasound for placenta localization.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that amniotic fluid samplers (amniocentesis trays) be classified into class II (performance standards). The Commissioner has reviewed the Panel's recommendation and has obtained additional information and data describing the application of amniotic fluid samplers. The literature states that amniocentesis represents a step toward the reduction of tragic births (Ref. 3) and can be performed without significant risk to the ultimate outcome of pregnancy (Ref. 4). The Commissioner recognizes that there are potential risks associated with amniocentesis, e.g., puncturing of the fetus and spontaneous abortion (Refs. 5, 6, and 7). These occurrences are rare and do not negate the value of amniocentesis.

The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Queenan, J. T., "Modern Management of The Rh Problem," Harper and Row, New York, 1977.

2. The NICHD National Registry for Amniocentesis Study Group, "Midtrimester Amniocentesis for Prenatal Diagnosis: Safety and Accuracy," *Journal of the American Medical Association*, 236(13):1471–1476, September 1976.

3. Goldstein A. I. and K. W. Dumars, "Minimizing the Risk of Amniocentesis for Prenatal Diagnosis," *Journal of the American Medical Association*, 237(13):1336–1338, March 1977.

4. Young, P. E., et al., "Amniocentesis for Antenatal Diagnosis: Review of Problems and Outcomes in a Large Series," *American Journal of Obstetrics and Gynecology*, 125(4):495–501, June 1976.

5. Karp, L. E. and P. W. Hayden, "Fetal Puncture During Midtrimester Amniocentesis," *Obstetrics and Gynecology*, 49(1):115–117, January 1977.

6. Broome, D. L., M. G. Wilson, B. Weiss, and B. Kellogg, "Needle Puncture of Fetus: A Complication of Second-Trimester Amniocentesis," *American Journal of Obstetrics and Gynecology*, 126(2):247–252, September 1976.

7. Philip, J. and J. Bang, "Outcome of Pregnancy after Amniocentesis for Chromosome Analysis," *British Medical Journal*, 2:1183–1184, October 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1550 as follows:

§ 884.1550 Amniotic fluid sampler (amniocentesis tray).

(a) *Identification.* An amniotic fluid sampler is a device used for amniocentesis (transabdominal aspiration of fluid from the amniotic sac). The sampler consists of disposable instruments, drapes, specimen containers, and other accessories on a tray.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1114]

[FR Doc. 79–9418 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03

[21 CFR Part 884]

Classification of Fetal Blood Samplers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fetal blood samplers into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices

(HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of fetal blood samplers:

1. Identification: A fetal blood sampler is a device used to obtain fetal blood transcervically through an endoscope by puncturing the fetal skin with a short-blade and drawing blood into a heparinized tube. The fetal blood pH is determined and used in the diagnosis of fetal distress and fetal hypoxia. The Panel previously considered this generic type of device under the name "fetal scalp blood sampler."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that fetal blood samplers be classified into class II (performance standards) because the Panel believes that a design standard must prevent the blade from cutting any further than a standardized tissue depth (e.g., by use of a blade guard) to protect the fetal scalp and brain or other presenting part. This design standard must also assure retention of the blade in the handle to prevent trauma to the fetus and uterus. The Panel also believes that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel recommends that to prevent infection the method of sterilization be stated in the device labeling. The Panel notes that, when this device is used with other devices as a system, the combination most be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also states that the use of this device is contraindicated in the presence of infection, Rh incompatibility, or fetal blood disorder. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The fetal blood sampler is used at many perinatal centers. At one hospital, 1,025 fetal blood samples were collected in 640 cases. In that group, two fetal deaths due to hemorrhage were reported, which could have been prevented if the device had had a blade guard. (Ref 1). Dr. E. Saling, a pioneer in the use of this device, reports no serious incidents in his experience with more than 8,000 cases (Ref. 2). Saling does note a slightly increased risk of infection for mother and child. The Panel cites extensive clinical use of this device by Saling, by Dr. A. E. Seeds of Cincinnati, and by Dr. R. W. Beard of London.

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Trauma, hemorrhage, or perforation: Breakage or incorrect dimensions of the blade could result in a part of the device injuring the fetus and uterus or puncturing the fetal brain. Trauma to mother or fetus could occur if the heparinized glass capillary tube fractures during the procedure. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient and fetus.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that fetal blood samplers be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m to 4 p.m., Monday through Friday.

1. Beard, R. W., et al., "Haemorrhage Following Fetal Blood Sampling," *Journal of Obstetrics and Gynecology of the British Commonwealth*, 73:860–861, 1966.

2. Saling, E., et al., "The Present Situation of Clinical Monitoring of the Fetus During Labor," *Journal of Perinatal Medicine*, 1:92–94, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1560 as follows:

§ 884.1560 Fetal blood sampler.

(a) *Identification.* A fetal blood sampler is a device used to obtain fetal blood transcervically through an endoscope by puncturing the fetal skin with a short blade and drawing blood into a heparinized tube. The fetal blood pH is determined and used in the diagnosis of fetal distress and fetal hypoxia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–115]

[FR Doc. 79–9419 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Transabdominal Amnioscopes (Fetoscopes) and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying transabdominal amnioscopes (fetoscopes) and accessories into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of transabdominal amnioscopes (fetoscopes) and accessories:

1 Identification: A transabdominal amnioscope is a device designed to permit direct visual examination of the fetus by a telescopic system via abdominal entry. The device is used to ascertain fetal abnormalities, to obtain fetal blood samples, or to obtain fetal tissue. This generic type of device may include the following accessories: trocar and cannula, instruments used through an operating channel or through a separate cannula associated with the amnioscope, light source and cables, and component parts.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority

3. Summary of reasons for recommendation: The Panel recommends that transabdominal amnioscopes be classified into class III. The Panel believes that because satisfactory performance has never been demonstrated, it is not possible to establish an adequate performance standard for this device. The procedure employing the transabdominal amnioscope should be done at a well-equipped medical center that has experienced personnel capable of diagnosing and treating potential complications. Informed patient consent and institutional review practices should be followed. This device will be very useful in expanding present knowledge of prenatal genetics. The risk to benefit ratio has been improving steadily (Ref. 1). The Panel believes that electrical safety standards are required to minimize the hazard of electrical shock. The Panel also stated that the light source must not present hot surfaces that could cause burns to internal tissues. The device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. Furthermore, the Panel believes that design standards are necessary to assure that the diameter of the scope is sufficiently small to prevent trauma and hemorrhage or induced abortion when the fetoscope is introduced transabdominally into the uterus. The Panel recommends that the method of sterilization be stated in the device labeling, to prevent infection. Although the above hazards can be controlled by a performance standard, the Panel believes that premarket approval is necessary to assure that each device design is effective. The Panel agrees that any invasive technique, except where delivery is imminent, presents a high risk to the fetus and pregnant patient. Additionally, the Panel notes that the device's use may be contraindicated if the placenta is on the anterior side of the uterus because, in this case fetoscopy may induce spontaneous abortion (Ref. 2). The Panel recommends that this risk be reduced by the use of ultrasound to locate fetal parts and placenta prior to its use. The Panel considers available information insufficient to establish standards to provide assurance of the safety and effectiveness of this device.

Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel also reviewed the literature on the device (Refs. 1 and 2). The Panel believes that clinical experience with the device is too limited to establish its safe and effective use (Ref. 2). Dr. Jordan Phillips, a Panel member who has had first-hand knowledge concerning its development, stated at the Obstetrical and Gynecological Device Classification Panel meeting on July 13, 1976, that although this device is beneficial in determining fetal anomalies (neural tube disorder) through direct visualization of the fetus or congenital defects through fetal blood sampling (Refs. 2 and 3), its use is considered a "risk procedure" at this time.

5. Risks to health: (a) Burns: Poor design or incorrect application of the device could result in tissue burns when the device contacts the patient's body. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (c) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (d) Trauma, hemorrhage, and perforation: Improper scope size of the device could result in mortal injury to the fetus. (e) Adverse tissue reaction: Material or substances in the device could result in a systemic or local tissue reaction when the device contacts the patient's tissue or the fetus. (f) Premature labor: Use of the device could result in premature labor, and possibly induced abortion, especially when the patient has an anterior placenta.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that transabdominal amnioscopes be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and has obtained additional data and information describing the application of transabdominal amnioscopes to examine the fetus visually and collect tissue samplings. The Commissioner notes additional characteristics of the device that can be controlled by performance standards. The needle must be sharp enough that it will not penetrate fetal membranes; the trocar within the cannula must be an exact fit so that no lip of metal will impede puncture of the uterus; and the cannula should be etched so that the user knows exactly how far the fetoscope within the uterus can be withdrawn without removing it completely (Ref. 4). However, the Commissioner is concerned about problems with the device that cannot be controlled by performance standards, namely the reported frequency of diagnostic error, failure of sample acquisition, and fetal loss (Ref. 1). The Commissioner believes that the device is purported or represented to be for a use (detection of fetal congenital abnormalities) that is of substantial importance in preventing impairment of human health. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because its safety and effectiveness have not yet been adequately determined. Moreover, the value of diagnostic information on fetal status may not outweigh the fetal risk (Ref. 5). Therefore, the device should be subject to premarket approval. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Alter, B. P., C. B. Modell, D. Fairweather, J. C. Hobbins, M. J. Mahoney, F. D. Frigoletto, A. S. Sherman, and D. G. Nathan, "Prenatal Diagnosis of Hemoglobinopathies," *New England Journal of Medicine*, 26:1437–43, 1976.

2. Phillips, J. M., "Fetoscopy: An Overview," *The Journal or Reproductive Medicine*, 15:69–72, 1975.

3. Summary Minutes of the Thirteenth Meeting of the Obstetrical and Gynecological Device Classification Panel, July 1976.

4. Morris, J. A., E. C. Davidson, J. J. Arce, J. E. Maidman, J. E. Brown, and R. Frazer, "Sampling the Fetoplacental Circulation: II.

Combined Laparoscopy-Fetoscopy in the Pregnant Ovine," *The American Journal of Obstetrics and Gynecology*, 128:279–86, 1977.

5. Phillips, J. M., "Fetoscopy: Its Genesis and Promise," *The Journal of Reproductive Medicine*, 21(37):115–122, September 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1600 as follows:

§ 884.1600 Transabdonimal amnioscope (fetoscope) and accessories.

(a) *Identification.* A transabdominal amnioscope is a device designed to permit direct visual examination of the fetus by a telescopic system via abdominal entry. The device is used to ascertain fetal abnormalities, to obtain fetal blood samples, or to obtain fetal tissue. This generic type of device may include the following accessories: trocar and cannula, instruments used through an operating channel or through a separate cannula associated with the amnioscope, light source and cables, and component parts.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1116]

[FR Doc. 79–9420 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Colposcopes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying colposcopes into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of colposcopes.

1. Identification: A colposcope is a device designed to permit direct viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. It is used to diagnose abnormalities and select areas for biopsy. This generic type of device may include a light source, cables, and component parts. The Panel includes in this generic type of device those devices which were named "colposcope" and "colpomicroscope."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that colposcopes be classified into class II (performance standards) because the Panel believes that electrical safety standards are required to minimize the hazard of electrical shock. The Panel also believes that material standards are necessary to assure adequate strength of the support structure to prevent trauma to the patient through breakage. The Panel notes that, when this device is used with other devices (e.g., the gynecologic surgical laser) as a system, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. Dr. Jordan Phillips, a Panel member, has had much experience with this device and has supplied literature on its history and use (Refs. 1 and 2).

5. Risks to health: (a) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (b) Trauma: Failure of the support structure of the device could result in a part of the device striking or injuring the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that colposcopes be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Benson, R. C., et al., "Current Obstetric and Gynecological Diagnosis and Treatment," Lange Publishers, Los Altos, Ca., p. 89, 1976.

2. Weese, W. H., "A Brief History of Colposcopy," *The Journal of Reproductive Medicine*, 16:209, May 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1630 as follows:

§ 884.1630 Colposcope.

(a) *Identification.* A colposcope is a device designed to permit direct viewing of the tissues of the vagina and cervix

by a telescopic system located outside the vagina. It is used to diagnose abnormalities and select areas for biopsy. This generic type of device may include a light source, cables, and component parts.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78–1117]

[FR Doc. 79–9421 Filed 4–2–79; 8:45 am]
BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Culdoscopes and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying culdoscopes and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of culdoscopes and accessories:

1. Identification: A culdoscope is a device designed to permit direct viewing of the organs within the peritoneum by a telescopic system introduced into the pelvic cavity through the posterior vaginal fornix. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include: trocar and cannula, instruments used through an operating channel, scope preheaters, light source and cables and components parts.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that culdoscopes and accessories be classified into class II (performance standards) because the Panel believes that electrical safety standards are required to minimize the hazards of electrical shock, especially from high frequency leakage during electrocoagulation. The Panel recommends thermal insulation of the device assembly to prevent burns from unsafe heat dissipation. The Panel also believes that a material standard is necessary to assure an adequate surface finish to prevent trauma to the vaginal tissues. The Panel states that the device materials contacting the internal tissues should meet a biocompatibility standard to prevent adverse tissue reaction. The Panel recommends that the method of sterilization be stated in the device labeling, to prevent infection. The Panel notes that when this device is used with other devices as a system, the combination must be compatible. The Panel also states that the use of the device is contraindicated during pregnancy. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device (Ref. 1). The Panel also reviewed medical literature stating that this device is safe and causes few complications, if contraindications are heeded and prescribed techniques are followed (Ref. 2).

5. Risks to health: (a) Burns: Poor design or incorrect application of the device could result in tissue burns when the device comes in contact with body tissues. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (c) Electrical shock: Malfunction and improper insulation of the device could result in electrical shock to the patient. (d) Adverse tissue reaction: Material or substances in the device could result in a local tissue or systemic reaction when the device comes in contact with the patient. (e) Truama and perforation: Surface burrs on the device could result in trauma or perforation of the tissues.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that culdoscopes and accessories be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation and has obtained additional data and information describing the application of culdoscopic technique in performing diagnostic and surgical procedures on the female reproductive organs. The Commissioner notes that culdoscopic technique is contraindicated in the presence of pelvic inflammatory disease, fixed cul-de-sac, pregnancy, obesity, endometriosis, abnormal growths, cardiorespiratory disease, or a previous hysterectomy (Refs. 2 through 5). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the Thirteenth Meeting of the Obstetrical and Gynecological Classification Panel, July 1976.

2. Glinter, K. P., and R. J. Nelson, "Gynecologic Endoscopy: Laparoscopy or Culdoscopy," *Journal of American Osteopathic Association*, 73:986, 1974.

3. Wortman, Judith, "Female Sterilization Using the Culdoscope," *Population Reports*, Series C (6):61–71, 1975.

4. Bank, A. H., "Culdoscopic Tubal Sterilization," *Fertility and Sterility*, 24(2):155–157, 1973.

5. Koetsawang, S., et al., "Comparison of Culdoscopic and Laparoscopic Tubal Sterilization," *American Journal of Obstetrics and Gynecology*, 124(6):601–606, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1640 as follows:

§ 884.1640 Culdoscope and accessories.

(a) *Identification.* A culdoscope is a device designed to permit direct viewing of the organs within the peritoneum by a telescopic system introduced into the pelvic cavity through the posterior vaginal fornix. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include trocar and cannula, instruments used through an operating channel, scope preheaters, light source and cables, and component parts.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1118]

[FR Doc. 79–9422 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M]

[21 CFR Part 884]

Classification of Transcervical Endoscopes (Amnioscopes) and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying transcervical endoscopes (amnioscopes) and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of transcervical endoscopes (aminoscopes) and accessories:

1. Identification: A transcervical endoscope is a device designed to permit direct viewing of the fetus and amniotic sac by means of an open tube introduced into the uterus through the cervix. The device may be used to visualize the fetus or amniotic fluid and to sample fetal blood or amniotic fluid. This generic type of device may include: obturators, instruments used through an operating channel, light sources and cables, and component parts. The Panel includes in this generic type of device those devices which were named "transcervical amnioscopes (and accessories)" and "fetal blood sampling endoscopes (and accessories)."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the transcervical endoscope (amnioscope) and accessories be classified into class II (performance standards) because the Panel believes that electrical safety standards are required to minimize the hazards of electrical shock. The Panel also states that the light source must not cause burns by presenting hot surfaces to internal tissues. The device materials contacting the body should meet a biocompatibility standard to prevent adverse tissue reaction. The Panel also believes that material standards are necessary to assure adequate surface finish and appropriate strength to prevent trauma to the amniotic sac and fetus. Furthermore, the Panel recommends that the method of sterilization be stated in the device labeling, to prevent infection. The Panel notes that when this device is used with other devices as a system, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also states that fetal blood sampling is contraindicated in the presence of infection, Rh incompatibility, or a history of blood coagulation disorders. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel also reviewed the literature on the original work by Saling, whose extensive clinical experience in perinatal centers demonstrates the safety of the procedure and the reliability of the device (Ref. 1).

5. Risks to health: (a) Burns: Poor design or incorrect application of the device could result in tissue burns if the device heats the patient's tissue. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (c) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (d) Trauma and perforation: Trauma to mother and fetus could occur if the heparinized glass capilliary tube fractures during the blood sampling procedure. (e) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient or fetus. (f) Ruptured membranes: Sharp or irregular edges of the device could result in an unintended rupture of the amniotic sac.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that transcervical endoscopes (amnioscopes) and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because

general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following infomation has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Saling, E., "Amnioscopy," *Clinical Obstetrics and Gynecology*, 9:478–495, 1966.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1660 as follows:

§ 884.1660 Transcervical endoscope (amnioscope) and accessories.

(a) *Identification.* A transcervical endoscope is a device designed to permit direct viewing of the fetus and amniotic sac by means of an open tube introduced into the uterus through the cervix. The device may be used to visualize the fetus or amniotic fluid and to sample fetal blood or amniotic fluid. This generic type of device may include obturators, instruments used through an operating channel, light sources and cables, and component parts.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1119]

[FR Doc. 79–9423 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Hysteroscopes and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hysteroscopes and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of hysteroscopes and accessories:

1. Identification: A hysteroscope is a device used to permit direct viewing of the cervical canal and the uterine cavity by a telescopic system introduced into the uterus through the cervix. It is used to perform diagnostic and surgical procedures other than sterilization. This generic type of device may include obturators and sheaths, instruments used through an operating channel, scope preheaters, light sources and cables, and component parts.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hysteroscopes and accessories be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure a fail-safe gas pressure tubing connection to the hysteroscopic insufflator to prevent inadvertent attachment to the laparoscopic insufflator, which could over-insufflate the uterus. The Panel believes that electrical safety standards are required to minimize the hazards of electrical shock, especially from high-frequency leakage during electrocoagulation. The Panel recommends thermal insulation of the device assembly to prevent burns from unsafe heat dissipation. The Panel believes that material standards are necessary to assure adequate surface finish and appropriate tensile strength to prevent cervical or uterine trauma. The Panel also states that device materials contracting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. When this device is used with other devices as a system, the combination must be compatible. The Panel recommends that the method of device sterilization be stated in the labeling to prevent infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that the use of the hysteroscope is contraindicated in the presence of hemorrhage, pelvic inflamatory disease, or profuse bleeding. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device (Ref. 1). The Panel also reviewed the medical literature, which establishes that the device should be used only in diagnostic and surgical procedures. There are insufficient data to conclude that the device is effective for sterilization (Ref. 2).

5. Risks to health: (a) Burns: Poor design or incorrect application of the device could result in tissue burns when the device heats the patient's tissue. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (c) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (d) Trauma, hemorrhage, and perforation: The structure of the device could result in a part of the device injuring or puncturing the patient's body. (e) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient. (f) Uterine rupture: Excessive pressure could result in uterine rupture if the laparoscopic insufflator is used with this device.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that hysteroscopes and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device (Refs. 3 and 4). Additional information and data obtained by the Commissioner support the Panel's conclusion that there are insufficient data available to write a performance standard for the use of the hysteroscope in sterilization techniques (Refs. 5 and 6).

The Commissioner is aware that no U.S. manufacturers label sterilization as an intended use for hysteroscopes. At the present time, hysteroscopic procedure to perform sterilization is considered an investigational procedure.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the Thirteenth Meeting of the Obstetric and Gynecologic Device Classification Panel, 1976.

2. Siegler, A. M. and E. Kemmann, "Hysteroscopy," *Obstetrical and Gynecological Survey,* 30(9), 1975.

3. Sciarra, J. J. and R. F. Valle, "Hysteroscopy: A Clinical Experience with 320 Patients," *American Journal of Obstetrics and Gynecology,* 127(4):340–348, 1977.

4. Sugimoto, O., "Hysteroscopic Diagnosis of Endometrial Carcinoma" *American Journal of Obstetrics and Gynecology,* 121(1):105–113, 1975.

5. Richart, R. M., et al., "Female Sterilization by Electrocoagulation of Tubal Ostia Using Hysteroscopy," *American Journal of Obstetrics and Gynecology,* 117(6):801–804, 1973.

6. Valle, R. F. and J. J. Sciarra, "Hysteroscopy," *in* "Gynecology and Obstetrics," Vol. III, Ch. 19, Harper and Row Publishers, Inc., Hagerstown, MD, pp. 1–12, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1690 as follows:

§ 884.1690 Hysteroscope and accessories.

(a) *Identification.* A hysteroscope is a device used to permit direct viewing of the cervical canal and the uterine cavity by a telescopic system introduced into the uterus through the cervix. It is used to perform diagnostic and surgical procedures other than sterilization. This generic type of device may include obturators and sheaths, instruments used through an operating channel, scope preheaters, light sources and cables, and component parts.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1120]

[FR Doc. 79–9424 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Hysteroscopic Insufflators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hysteroscopic insufflators into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issued a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of hysteroscopic insufflators:

1. Identification: A hysteroscopic insufflator is a device designed to distend the uterus by filling the uterine cavity with a liquid or gas to facilitate viewing with a hysteroscope. The Panel imcludes in this generic type of device those devices identified as "uterine insufflation cannula (and accessories)" and "hysteroscopic insufflator."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hysteroscope insufflators be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure that the device design incorporates a fail-safe means (for example, a major source shutoff control with a reducing valve) to prevent the possibility of excessive pressure. The Panel states that the design of the gas pressure tubing connector must prevent the inadvertant attachment to laparoscopic equipment. The Panel also believes that measurement standards would assure the accuracy and resolution of controls and indictators for flow rate, pressure, and volume. These precautions are necessary to avoid hazards from overinsufflation of the uterus, including uterine rupture, embolus induction, tachycardia, cardiac arrhythmia, and cardiac arrest. The Panel also believes that the device materials contacting the body should

meet a biocompatibility standard to prevent adverse tissue reaction. Electrical safety standards are required in order to minimize the hazards of electrical shock. The Panel also recommends that the method of sterilization be stated in the device labeling to prevent infection. The Panel notes that when this device is used with other devices as a system, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over the above characteristics. The Panel noted that use of the device during pregnancy is contraindicated. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel also reviewed the literature on the device. The current literature on the device. The current literature recommends that the pressure of the device not exceed 200 millimeters of Hg (mercury) and that the flow-rate of the gas be maintained between 60 and 80 milliliters of gas per minute (Refs. 1 and 2). The laparoscopic insufflator can deliver at least 1 liter of gas per minute (Ref. 2). The laparoscopic insufflator can deliver at least 1 liter of gas per minute (Ref. 2); therefore, adequate safeguards must be employed to prevent the attachment of hysteroscopic insufflator tubing to the mechanism for the laparoscopic insufflator.

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Adverse tissue reaction: Material of the tubing could cause a systemic or local tissue reaction when contact is made with the patient's body. (d) Uterine rupture, cardiac abnormalities, and emboli induction: Excessive pressure of the device could result in uterine rupture, cardiac abnormalities, and emboli induction if the device does not have fail-safe measures to control the pressure.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that hysteroscopic insufflators be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Bartsich, E. G. and T. F. Dillon, "Carbon Dioxide Hysteroscopy," *American Journal of Obstetrics and Gynecology*, 124(7):746–750, April 1976.

2. Siegler, A. M. and E. Kemmann, "Hysteroscopy," *Obstetrical and Gynecological Survey, 30(9), 1975.*

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1700 as follows:

§ 884.1700 Hysteroscopic insufflator.

(a) *Identification.* A hysteroscopic insufflator is a device designed to distend the uterus by filling the uterine cavity with a liquid or gas to facilitate viewing with a hysterscope.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1121]

[FR Doc. 79–9425 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–83–M

[21 CFR Part 884]

Classification of Gynecologic Laparoscopes and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gynecologic aparoscopes and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstertrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of gynecologic laparoscopes and accessories:

1. Identification: A gynecologic laparoscope is a device used to permit direct viewing of the organs within the peritoneum by a telescopic system introduced through the abdominal wall. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include: trocar and cannula, instruments used through an operating channel, scope preheater, light source and cables, and component parts. The Panel includes in this generic type of device those devices identified as "ob-gyn laparoscope and accessories" and "endoscopic light source."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a perfomance standard for this device be high priority.

3. Summary of reasons for recommendation: The Panel recommends the gynecologic laparoscope and accessories be classified into class II (performance standards) because the Panel believes that electrical safety standards are required to minimize the hazards of electrical shock.

especially from high frequency leakage during electrocoagulation. The Panel recommends thermal insulation of the device assembly to prevent burns from unsafe heat dissipation. The device materials contacting the internal tissues should meet a biocompatibility standard to prevent and adverse tissue reaction. The Panel believes that material standards are necessary to assure an adequate surface finish and appropriate tensile strength to prevent trauma to the patient. The Panel recommends that the method of sterilization be stated in the device labeling, especially the use of a biocompatible soluion to sterilize the gas pressure tubing. The Panel notes that when this device is used with other devices as a system, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also states that the use of the device is contraindicated for cardiac or pulmonary patients, in the presence of diaphragmatic hernia, bowel obstruction, or abdominal mass, and during the second or third trimester of pregnancy. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. Over 300,000 cases of laparoscopic use, in which a very low incidence of danger was noted, have been compiled by the American Association of Gynecologic Laparoscopists (AAGL) (Refs. 1 and 2). The Panel considered separately the endoscopic light source, and noted the reported danger of electrical shock and burn associated with its use (Ref. 3).

5. Risks to health: (a) Burns: Poor design or incorrect application of the device could result in tissue burns when the device comes in contact with the patient. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (c) Electrical shock: Malfunction of the device could result in electrical shock to the patient or to the operator. (d) Trauma and perforation: Surface roughness of the device could result in a part of the device injuring the patient. (e) Adverse tissue reaction: Material in the device could result in a systemic or local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that gynecologic laparoscopes and accessories be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation concerning the laparoscope and accessories and has obtained additional data and information describing the application of the gynecologic laparoscope. The laparoscopic procedure is safe with few complications if contraindications are needed and prescribed techniques are followed (Refs. 4 and 5). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Phillips, J. M., et al., "Gynecologic Laparoscopy in 1975," *Journal of Reproductive Medicine*, 16:105–117, 1976.

2. Phillips, J. M., et al., "The Impact of Laparoscopy, Hysteroscopy, Fetoscopy and Culdoscopy on Gynecologic Practice," *Journal of Reproductive Medicine*, 16:187–190, 1976.

3. Neufeld, G. R., et al., "Electrical Burns During Laparoscopy," *Journal of the American Medical Association*, 226:1465, 1973.

4. Glinter, K. P. and R. J. Nelson, "Gynecologic Endoscopy: Laparoscopy or Culdoscopy?" *Journal of the American Osteopathic Association*, 73:986–994, 1974.

5. Reingold, L. A., "Guide to Equipment Selection for M/F Sterilization Procedures," *Population Reports*, Special Topics Monongraphs No. 1, Sept. 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1720 as follows:

§ 884.1720 Gynecologic laparoscope and accessories.

(a) *Identification.* A gynecologic laparoscope is a device used to permit direct viewing of the organs within the peritoneum by a telescopic system introduced through the abdominal wall. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include: trocar and cannula, instruments used through an operating channel, scope preheater, light source and cables, and components parts.

(b) *Classification.* Class II (performance standards).Q02

Interested persons may, on or before June 4, 1979, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

WILLIAM F. RANDOLPH,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1122]

FR Doc. 79–9426 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Laparoscopic Insufflators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying laparoscopic insufflators into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulations. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of laparoscopic insufflators:

1. Identification: a laparoscopic insufflator is a device used to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that laparoscopic insufflator be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure that the laparoscopic insufflator incorporates a fail-safe means (e.g., a major source shut-off control with a reducing valve) to prevent the possibility of excessive pressure. The Panel states that the design of the gas pressure tubing connector must prevent the inadvertent attachment to hysteroscopic equipment. The Panel also recommends that the labeling of the device state that it is for laparoscopic use only. The Panel also believes measurement standards would assure the accuracy and resolution of controls and indicators for flow rate, pressure, and volume. These precautions are necessary to avoid the hazards of damage to internal organs including induction of gas emboli in the blood, cardiac arrest, cardiac arrhythmia, and tachycardia. The Panel also believes that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction: this includes a biocompatible solution for sterilization of the gas pressure tubing. Electrical safety standards are required to minimize the hazards of electrical shock. The Panel also recommends that, to prevent infection, the method of sterilization be stated in the device labeling. The Panel notes that when this advice is used with other devices as a system, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel noted that in a 1974 survey 90 percent of the respondents used carbon dioxide as an insufflating medium (Ref. 1). Dr. Jordan Phillips, a Panel member, provided detailed information concerning the risks and means of control of this device (Ref. 1). Dr. Phillips surveyed the choice of type, quantity, and gas pressure used in over 8,000 laparoscopic procedures performed by 886 laparoscopists (Ref. 2).

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Uterine rupture, cardiac abnormalities, and embolus induction:

Excessive pressure from the device could result in uterine rupture, cardiac abnormalities, and embolus induction if the device does not include fail-safe measures to control the pressure.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that laparoscopic insufflators be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation concerning the laparoscopic insufflators and has obtained additional data and information supporting the Panel recommendation concerning the need for a fail-safe mechanism to prevent excessive pressure that may damage internal organs (Ref. 3). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the Thirteenth Meeting of the Obstetric and Gynecologic Classification Panel, July 1976.

2. Phillips, J. M., et al., "Survey of Gynecologic Laparoscopy for 1974," *Journal of Reproductive Medicine*, 15(2):45–50, 1975.

3. Reingold, L. A., "Guide to Equipment Selection for M/F Sterilization Procedures," Population Reports, Special Topics Monographs, No. 1, Sept. 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart B by adding new § 884.1730 as follows:

§ 884.1730 Laparoscopic insufflator.

(a) *Identification.* A laparoscopic insufflator is a device used to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1123]

[FR Doc. 79–9427 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Obstetric Data Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying obstetric data analyzers into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–

65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of obstetric data analyzers:

1. Identification: An obstetric data analyzer is a device used to interpret fetal status during labor and to warn of possible fetal distress by analyzing electronic signal data obtained from fetal or maternal electronic or other monitors. This generic type of device includes signal analysis and display equipment, electronic interfaces for other equipment, and power supplies and component parts. The Panel previously considered this generic type of device under the name "fetal status data analyzer."

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the obstetric data analyzer be classified into class III because satisfactory performance of the device has never been demonstrated. The Panel believes that it is not possible to establish an adequate performance standard for this device. Although electrical standards would be sufficient to control the electrical shock hazard, the device design presents an inherent risk of misdiagnosis of fetal status. Because the information provided can have a substantial impact on the health care of the patient and her fetus, the device's design must guarantee that the signals generated accurately reflect physiological conditions and that the device comes to the correct conclusion. The device may be used as a substitute for human judgment on a critical matter, and it therefore must not err. For example, on the basis of erroneous data from the device, the physician may order an unnecessary caesarean section. Accordingly, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the lack of safety and effectiveness data for this relatively unproven device.

5. Risks to health: (a) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (b) Misdiagnosis: Inadequate design or calibration of the device could lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment which places the fetus and patient at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that obstetric data analyzers be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and has obtained additional information and data describing the application of automatic analysis techniques to the determination of possible fetal distress. The technique is new, and very little definitive information is available. It is reasonable to expect that as algorithms are developed and tested, confidence in automatic analysis will increase (Ref. 1). The Commissioner has described this generic type of device to exclude patient monitors, imagers, and display devices which can not perform an interpretative function but which have an alarm that sounds when a preset threshold value is crossed.

The Commissioner believes that the device is purported or represented to be for a use (diagnosis of fetal distress) that is of substantial importance in preventing impairment of human health. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because the physician may decide, based on information from the obstetric data analyzer, to take a course of action which could put the fetus or mother in unreasonable jeopardy. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Sureau, C., "The Clinical Use of Computers in Fetal Heart Rate Monitoring," *in* "Perinatal Medicine," 4th European Congress of Perinatal Medicine, Prague, August 1974, Edited by Stembera, Z. K., K. Polacek, and V. Sabata; G. Thieme, Stuttgart; Avicenum, Prague, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 by adding new Subpart C and new § 884.2050 as follows:

Subpart C—Obstetrical and Gynecological Monitoring Devices

§ 884.2050 Obstetric data analyzer.

(a) *Identification.* An obstetric data analyzer is a device designed to interpret fetal status during labor and to warn of possible fetal distress by analyzing electronic signal data obtained from fetal or maternal electronic or other monitors. This generic type of device includes signal analysis and display equipment, electronic interfaces for other equipment, and power supplies and component parts.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1977, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1124]

[FR Doc. 79-9428 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Obstetric-Gynecologic Ultrasonic Imagers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying obstetric-gynecologic ultrasonic imagers into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The

effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of obstetric-gynecologic ultrasonic imagers:

1. Identification: An obstetric-gynecologic ultrasonic imager is a device designed to transmit and receive ultrasonic energy into and from a female patient by pulsed echoscopy. This device is used to provide a visual representation of some physiological or artificial structure, or of a fetus, for diagnostic purposes during a limited period of time. This generic type of device may include signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, coupling gel, and component parts. This generic type of device does not include devices used to monitor the changes in some physiological condition over long periods of time. The Panel includes in this generic type of device those devices identified as "ultrasonic fetal imager," "acoustical fetal holograph," "ultrasonic fetal head diameter measuring instrument," and "ultrasonic contraceptive intrauterine device locator."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that obstetric-gynecologic ultrasonic imagers be classified into class II (performance standards) because the Panel believes that standards are necessary to assure that the emitted ultrasonic energy does not reach levels of radiation unsafe to the patient or fetus. Ultrasonic imagers are sometimes used to measure fetal dimensions when determining its gestational age, and the Panel believes that the image produced must meet certain measurement requirements to prevent misdiagnosis. The Panel also believes that electrical safety standards are required to minimize the hazards of electrical shock. The Panel notes that when this device is used with other devices as a system, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also recommends that the accuracy, reproducibility, and limitations of the device's measurements be stated in the labeling. The Panel initially recommended that the device be classified into class II (premarket approval) because long-term effects of diagnostic ultrasound are not known. The Panel changed its recommendation for diagnostic ultrasonic devices, from class III to class II after considering the benefits and risks from the use of these devices, and the available data. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on an extensive review of the data presented to the Panel and to the Biologic Effects of Ultrasound Subcommittee (BEUS) (Ref. 1). The extensive experience of some Panel members reveals no observable damage to mammalian tissue occurring when the transducer power output is below 100 milliwatts per square centimeter (spatial peak, temporal average) of ultrasonic energy with a time exposure normal for diagnostic purposes. This conclusion has been published in a statement of the American Institute of Ultrasound in Medicine (Ref. 2). To the Panel's knowledge, no currently marketed device exceeds that power limit.

Furthermore, a followup of children exposed to diagnostic doses in the womb shows no evidence of deleterious effects (Ref. 1). The Panel does recommend, however, that fetal exposure (duration, area, and output intensity) be minimized (consistent with obtaining necessary clinical information) because optimum power levels, maximum exposure times, and long-term effects upon the fetus from routine clinical use are unknown at this time. A technical committee chairman from the National Electrical Manufacturers Association (NEMA) presented a proposal for diagnostic ultrasonic equipment parameters to the BEUS (Ref. 3). The Panel recommends that the NEMA maximum allowable values of ultrasonic energy and parameters suggested for the labeling of ultrasonic devices be used as an interim guideline for developing a performance standard for obstetric and abdominal diagnostic ultrasonic devices.

5. Risks to health: (a) Tissue damage: The device's ultrasonic energy may produce tissue damage if the energy output is not controlled. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Misdiagnosis: Inadequate design or calibration of the device could lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that obstetric-gynecologic imagers be classified into class II (performance standards). Stratmeyer's review (Ref. 4) of the possible biological effects of ultrasound includes references to investigations showing that exposures to ultrasonic energy similar to those used in obstetric-gynecologic imagers may cause biological effects in laboratory animals. Although those investigations are cause for concern, the Commissioner regards them as inconclusive at this time. The studies have yet to be verified, and some investigators question the methods or findings of these investigations or their applicability to humans.

The Biological Effects of Ultrasound Subcommittee of FDA's Obstetrical and Gynecological Device Classification Panel has reviewed the possible adverse effects of diagnostic ultrasound devices. (The Subcommittee was established because of FDA's special concerns about the obstetrical use of ultrasound, based upon several studies involving laboratory animals that showed various biological effects from prenatal ultrasound exposures (Ref. 4).) The Subcommittee concluded that there is sufficient information available to establish a standard for diagnostic ultrasound devices generally (Refs. 5, 6, and 7).

In the Federal Register of February 13, 1979 (44 FR 9542), FDA published a notice of intent in the Federal Register announcing that it is considering an action program to reduce exposure to diagnostic ultrasound as much as practicable, consistent with the need for essential diagnostic information. One action the agency is considering is promulgation of a performance standard under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602, 42 U.S.C. 2636 et seq.).

The agency believes that a performance standard under the Radiation Control for Health and Safety Act may be necessary for obstetric-gynecologic imagers because general controls by themselves may be

insufficient to control the risks to health. The agency also believes that there is sufficient information to establish a standard that will provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Nyborg, W. L., "Minimum Thresholds for Bio-Effects of Ultrasound," Unpublished paper, Attachment E to Summary Minutes of the Biologic Effects of Ultrasound Subcommittee, Panel on Review of Obstetrical-Gynecological Devices, January 1976.

2. Bio-Effects Committee, "AIUM Committee Report," *Reflections*, 3(1):18, 1977.

3. Buxbaum, C., "Diagnostic Ultrasonic Equipment Parameters: Recommendations of the Technical Committee * * * October 22, 1976," Unpublished paper, Attachment E to Obstetrical and Gynecological Device Panel Classification Report, November 1977.

4. Stratmeyer, M. E., "Research Directions in Ultrasound Bioeffects—A Public Health View," Symposium on Biological Effects and Characterizations of Ultrasound Sources, June 2 and 3, 1977, pp. 240–245, HEW Publication (FDA) 78–8048.

5. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB–GYN Device Classification Panel (First Meeting), Jan. 22–23, 1976.

6. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB–GYN Device Classification Panel (Second Meeting), Oct. 28, 1976.

7. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB–GYN Device Classification Panel (Third Meeting), Oct. 4, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2225 as follows:

§ 884.2225 Obstetric-gynecologic ultrasonic imager.

(a) *Identification.* An obstetric-gynecologic ultrasonic imager is a device designed to transmit and receive ultrasonic energy into and from a female patient by pulsed echoscopy. This device is used to provide a visual representation of some physiological or artificial structure, or of a fetus, for diagnostic purposes during a limited period of time. This generic type of device may include the following: Signal analysis and display equipment, electronic interfaces for other epuipment, patient and equipment supports, coupling gel, and component parts. This generic type of device does not include devices used to monitor the changes in some physiological condition over long periods of time.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office beteen the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1125]

[FR Doc. 79–9429 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Fetal Cardiac Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fetal cardiac monitors into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Coments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of fetal cardiac monitors:

1. Identification: A fetal cardiac monitor is a device designed to separate fetal heart signals from maternal heart signals by analyzing electrocardiographic signals (electrical potentials generated during contraction and relaxation of heart muscle) obtained from the maternal abdomen with external electrodes or from another monitor. The device is used to ascertain fetal heart activity during pregnancy and labor. This generic type of device may include an alarm that signals when the heart rate crosses a preset threshold. The Panel includes in this generic type of device those devices identified as "fetal cardiotachometer (with sensors)" and "fetal electrocardiographic monitor."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that fetal cardiac monitors be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure that the device effectively indicates the fetal heart rate. The Panel believes that fetal cardiac monitors must meet certain measurement requirements to assure that they produce an accurate heart rate corresponding to the actual physiological condition. Also, electrical safety standards are necessary to minimize the hazards of electrical shock. The Panel notes that when this device is used with other devices as a system, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also recommends that the accuracy, reproducibility, and limitations of the device be stated in the labeling. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge

of, and extensive experience with, the device (Ref. 1).

5. Risks to health: (a) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (b) Misdiagnosis: Inadequate design of the device can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that fetal cardiac monitors be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

FDA's general concerns about fetal monitoring apply to fetal cardiac monitors. These concerns are described in proposed § 884.2740 regarding the classification of perinatal monitoring systems published elsewhere in this issue of the **Federal Register**.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the First Meeting of the Fetal Monitoring Devices Subcommittee of the Obstetrical and Gynecological Device Classification Panel, November 1976.

Therefore under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2600 as follows:

§ 884.2600 Fetal cardiac monitor.

(a) *Identification.* A fetal cardiac monitor is a device designed to separate fetal heart signals from maternal heart signals by analyzing electrocardiographic signals (electrical potentials generated during contraction and relaxation of heart muscle) obtained from the maternal abdomen through electrodes or through another monitor. The device is used to ascertain fetal heart activity during pregnancy and labor. This generic type of device may include an alarm that signals when the heart rate crosses a preset threshold.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1128]

[FR Doc. 79–9430 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Fetal Electroencephalographic Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fetal electroencephalographic monitors into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of fetal electroencephalographic monitors:

1. Identification: A fetal electroencephalographic monitor is a device used to detect, measure, and record in graphic form (by means of one or more electrodes placed transcervically on the fetal scalp during labor) the rhythmically varying electrical skin potentials produced by the fetal brain. The Panel previously considered this generic type of device under the name "fetal electroencephalograph (and accessories)."

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that electroencephalographic monitors be classified into class III (premarket approval) because the Panel believes that satisfactory performance has never been demonstrated. The Panel believes that certain characteristics of this device could be controlled by performance standards. Electrical safety standards could minimize the hazards of electrical shock. Proper sterilization procedures can prevent infection. Measurement standards can assure accurate indications of the physiologic signals. The device materials contacting the fetus and mother should meet a biocompatibility standard to prevent adverse tissue reaction. The Panel believes, however, that performance standards alone will not provide reasonable assurance of the safety and effectiveness of the device. Fetal electroencephalography is a relatively new fetal-monitoring technique, and there is not sufficient information to establish a standard to provide the needed assurance of proper performance. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the fact that fetal electroencephalographic monitoring is a relatively new method of brain function

evaluation during birth. Its sensitivity and applicability in the field of the fetal brain research remains to be established because clinical experience is too limited to ascertain its safe and effective use. Rosen and Peltzman, who are performing the major research on this device, are continuing with further controlled studies (Refs. 1 and 2).

5. Risks to health: (a) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (b) Misdiagnosis: Inadequate design of the device can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the fetus and patient at risk unnecessarily. (c) Adverse tissue reaction: Material in the device could result in a systemic or local tissue reaction when the device comes in contact with the patient. (d) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that the fetal electroencephalographic monitor be classified into class III (premarket approval). The Commissioner believes that the device is purported to represented to be a use (diagnosis of fetal brain dysfunction) that is of substantial importance in preventing impairment of human health. The Commissioner has reviewed additional data on fetal electroencephalography (FEEG). FEEG is considered a new technique used to evaluate perinatal status. Criteria for diagnosis are still in the developing stages (Ref. 3). The Commissioner believes that the device presents a potential unreasonable risk of injury or illness to the patient if practitioners rely upon the information derived from the device to diagnose conditions which correspond to fetal distress. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

FDA's general concerns about fetal monitoring apply to fetal encephalographic monitors. These concerns are described in proposed § 884.2740 regarding the classification of perinatal monitoring systems published elsewhere in this issue of the **Federal Register.**

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Peltzman, P., P. J. Goldstein, and R. Battagin, "Optical Analysis of the Fetal electroencephalogram," *American Journal of Obstetrics and Gynecology,* 116(7): 957–962, 1973.

2. Rosen, M. G., J. J. Scibetta, and C. J. Hochberg, "Fetal Electroencephalograph: IV. The FEEG During Spontaneous and Forceps Births," *(Obstestrics and Gynecology,* 42(2): 283–289, 1973.

3. "Borgstedt, A. D., et al., "Fetal Electroencephalography," *American Journal of Diseased Children,* 129:35–38, January 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2620 as follows:

§ 884.2620 Fetal electroencephalographic monitor.

(a) *Identification.* A fetal electroencephalographic monitor is a device used to detect, measure, and record in graphic form (by means of one of more electrodes placed transcervically on the fetal scalp during labor) the rhythmically varying electrical skin potentials produced by the fetal brain.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for the Regulatory Affairs.

[Docket No. 78N–1127]

[FR Doc. 79-9431 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Fetal Phonocardiographic Monitors and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fetal phonocardiographic monitors and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classificational Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTRACT:

Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of fetal phonocardiographic monitors and accessories:

1. Identification: A fetal phonocardiographic monitor is a device designed to detect, measure, and record fetal heart sounds electronically, in graphic form, and noninvasively, to ascertain fetal condition during labor. This generic type of device includes the following accessories: signal analysis and display equipment, patient and equipment supports, and other component parts. The Panel previously considered this generic type of device under the name "fetal phonocardiograph monitor."

2. Recommended classification: Class II (performance standards). The Panel

recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that fetal phonocardiographic monitors and accessories be classified into class II (performance standards) because electrical safety standards are required to minimize the hazards of electrical shock. The Panel believes that design standards are necessary to assure that this device can differentiate fetal heart sounds from other physiologic sounds (i.e., maternal respiration or maternal heart sounds). Measurement standards are required to assure an accurate indication of fetal heart rate. When this device is used with other devices, the combination must be compatible. The Panel believes that general controls alone will not provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a performance standard to provide such assurance.

4. Summary of data on which the recommendation is based: The panel based its recommendation on experience with, and personal knowledge of, the device (Ref. 1). This device has been safely used for several years in more than 5 million cases in hospitals and perinatal centers. The Panel reviewed the literature on the device, citing an article which shows the commonplace use of the phonocardiographic monitor as an initial noninvasive method of fetal monitoring (Ref. 2).

5. Risks to health: (a) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (b) Misdiagnosis: Inadequate design of the device can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that fetal phonocardiographic monitors and accessories be classified into class II (performance standards). The Commissioner notes that this device, when properly used, is not emitting energy into the patient, but rather receives and transduces physiologic signals from the body of the patient. The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

FDA's general concerns about fetal monitoring apply to fetal phonocardiographic monitors. These concerns are described in proposed § 884.2740 regarding the classification of perinatal monitoring systems published elsewhere in this issue of the Federal Register.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the First Meeting of the Fetal Monitoring Devices Subcommittee of the Obstetrical and Gynecological Device Classification Panel, November 1976.

2. Gabert, H. A. and M. A. Stenchever, "Continuous Electronic Monitoring of Fetal Heart During Labor," *American Journal of Obstetrics and Gynecology* 115:7, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2640 as follows:

§ 884.2640 Fetal phonocardiographic monitor.

(a) *Identification.* A fetal phonocardiographic monitor is a device designed to detect, measure, and record fetal heart sounds electronically, in graphic form, and noninvasively, to ascertain fetal condition during labor. This generic type of device includes the following accessories: signal analysis and display equipment, patient and equipment supports, and other component parts.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–9432 Filed 4–2–79; 8:45 am]
BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Fetal Ultrasonic Monitors and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fetal ultrasonic monitors and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one of more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of fetal ultrasonic monitors and accessories:

1. Identification: A fetal ultrasonic monitor is a device designed to transmit and receive ultrasonic energy into and from the pregnant woman, usually by means of continuous wave (doppler) echoscopy. The device is used to represent some physiological condition or characteristic as a measured value, over a period of time (e.g., perinatal monitoring during labor) or in an immediately perceptible form (e.g., use of the ultrasonic

stethoscope). This generic type of device includes the following accessories: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, and component parts. The generic type of device does not include devices (imagers) used to monitor some relatively unchanging physiological structure or interpret a physiological condition, but does include devices which may be set to alarm automatically at a predetermined threshhold value. The Panel includes in this generic type of device those devices identified as "ultrasonic fetal arterial pressure monitor," "ultrasonic blood flow monitor," "ultrasonic fetal heart rate monitor," "ultrasonic fetal heart sound monitor (ultrasonic stethoscope)," "ultrasonic fetal heart valve movement monitor," and "ultrasonic hemic sound monitor."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that fetal ultrasonic monitors and accessories be classified into class II (performance standards) because the Panel believes that standards are necessary to assure that the emitted ultrasonic energy does not reach radiation levels unsafe to the patient or fetus. The Panel believes that the fetal ultrasonic monitor must meet certain measurement requirements to assure that it produces signals corresponding to the physiological condition. Also, electrical safety standards are necessary to minimize the hazards of electrical shock. The Panel notes that when this device is used with other devices as a system, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also recommends that the accuracy, reproducibility, and limitations of the device's measurements be stated in the labeling. The Panel initially recommended that the device be classified into class III (premarket approval) because long-term effects of diagnostic ultrasound are not known. The Panel changed its recommendations for diagnostic ultrasonic devices from class III to class II after considering the benefits and risks from the use of these devices, and the available data. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on an extensive review of the data on this device presented to the Panel and to the Biologic Effects of Ultrasound Subcommittee (BEUS) (Ref. 1). These data, in conjunction with the extensive experience of some Panel members, reveal no observable damage to tissue occurring when the transducer power output is below 100 milliwatts per square centimeter (spatial peak, temporal average) of ultrasonic energy with a time exposure normal for diagnostic purposes. This conclusion has been published in a statement of the American Institute of Ultrasound in Medicine (Ref. 2). To the Panel's knowledge, no currently marketed device exceeds that power limit. Furthermore, a followup of children exposed to diagnostic doses in the womb shows no evidence of deleterious effects (Ref. 1). However, the Panel does recommend that fetal exposure (duration, area, and output intensity) be minimized (consistent with obtaining necessary clinical information) because optimum power levels, maximum exposure times, and long-term effects upon the fetus from routine clinical use are unknown at this time. A technical committee chairman from the National Electrical Manufacturers Association (NEMA) presented a proposal for diagnostic ultrasonic equipment parameters to the BEUS (Ref. 3). The Panel recommends that the NEMA maximum allowable values of ultrasonic energy and parameters suggested for the labeling of ultrasonic devices be used as an interim guideline for developing a performance standard for obstetric and abdominal diagnostic ultrasonic devices.

5. Risks to health: (a) Tissue damage: the device's ultrasonic energy may produce tissue damage if the energy output is not controlled. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Misdiagnosis: Inadequate design or calibration could lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient and fetus at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that fetal ultrasonic monitors and accessories be classified into class II (performance standards). Stratmeyer's review (Ref. 4) of the possible biological effects of ultrasound includes references to investigations showing that exposures of ultrasonic energy similar to those used in fetal ultrasonic monitors may cause biological effects in laboratory animals. Although those investigations are cause for concern, the Commissioner regards them as inconclusive at this time. The studies have yet to be verified, and some investigators question the methods or findings of these investigations or their applicability to humans.

The Biological Effects of Ultrasound Subcommittee of FDA's Obstetrical and Gynecological Device Classification Panel has reviewed the possible adverse effects of diagnostic ultrasound devices. (The Subcommittee was established because of FDA's special concerns about the obstetrical use of ultrasound, based upon several studies involving laboratory animals that showed various biological effects from prenatal ultrasound exposures (Ref. 4).) The Subcommittee concluded that there is sufficient information available to establish a standard for diagnostic ultrasound devices generally (Refs. 5, 6, and 7).

In the **Federal Register** of February 13, 1979 (44 FR 9542), FDA published a notice of intent in the **Federal Register** announcing that is is considering an action program to reduce exposure to diagnostic ultrasound as much as practicable, consistent with the need for essential diagnostic information. One action the agency is considering is promulgation of a performance standard under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602, 42 U.S.C. 2636 et seq.).

The agency believes that a performance standard under the Radiation Control for Health and Safety Act may be necessary for fetal ultrasonic monitors and accessories because general controls by themselves may be insufficient to control the risks to health. The agency also believes that there is sufficient information to establish a standard that will provide reasonable assurance of the safety and effectiveness of the device.

FDA's general concerns about fetal monitoring apply to fetal ultrasonic monitors and accessories. These concerns are described in proposed § 884.2740 regarding the classification of perinatal monitoring systems published elsewhere in this issue of the **Federal Register.**

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Nyborg, W. L., "Minimum Thresholds for Bio-Effects of Ultrasound," unpublished paper, Attachment E to Summary Minutes of the First Meeting of the Biologic Effects of Ultrasound Subcommittee, Panel on Review of Obstetrical-Gynecological Devices, January 1976.

2. Bio-Effects Committee, "AIUM Committee Report," *Reflections,* 3(1):18, 1977.

3. Buxbaum, C., "Diagnostic Ultrasonic Equipment Parameters: Recommendation of the Technical Committee * * * October 22, 1976," unpublished paper, Attachment E to Obstetrical and Gynecological Device Panel Classification Report, November 1977.

4. Stratmeyer, M. E., "Research Directions in Ultrasound Bioeffects—A Public Health View," Symposium on Biological Effects and Characterizations of Ultrasound Sources, June 2 and 3, 1977, pp. 240–245, HEW Publications (FDA) 78–8048.

5. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB–GYN Device Classification Panel (First Meeting), Jan. 22–23, 1976.

6. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB–GYN Device Classification Panel (Second Meeting), Oct. 28, 1976.

7. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB–GYN Device Classification Panel (Third Meeting), Oct. 4, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2660 as follows:

§ 884.2660 Fetal ultrasonic monitor and accessories.

(a) *Identification.* A fetal untrasonic monitor is a device designed to transmit and receive ultrasonic energy into and from the pregnant woman, usually by means of continuous wave (doppler) echoscopy. The device is used to represent some physiological condition or characteristic in a measured value over a period of time (e.g., perinatal monitoring during labor) or in an immediately perceptible form (e.g., use of the ultrasonic stethoscope). This generic type of device includes the following accessories: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, and component parts. This generic type of device does not inlcude devices used to image some relatively unchanging physiological structure or interpret a physiological condition, but does include devices which may be set to alarm automatically at a predetermined threshold value.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1129]

[FR Doc. 79–9433 Filed 4–2–79; 8:45 am]
BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Fetal Scalp Circular (Spiral) Electrodes and Applicators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fetal scalp circular (spiral) electrodes and applicators into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fetal scalp circular (spiral) electrodes and applicators:

1. Identification: A fetal scalp circular (spiral) electrodes and applicator is an obstetrical device used to obtain a fetal electrocardiogram during labor and delivery. It establishes electrical contact between fetal skin and an external monitoring device by a shallow subcutaneous puncture of fetal scalp tissue with a curved needle or needles. This device includes nonreusable spiral electrodes and reusable circular electrodes. The Panel included in this generic type of device those devices identified as "nonreusable fetal scalp spiral electrode" and "fetal scalp electrode applicator."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that fetal scalp circular (spiral) electrodes and applicators be classified into class II (performance standards) because the Panel believes that device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel believes that design standards are necessary to permit only limited penetration of the electrode in order to present tissue damage to the fetal brain. The design should also permit optimal attachment and removal of electrode to minimize trauma to the fetal scalp or other presenting part. The Panel recommends that the method of sterilization be stated in the labeling to prevent infection and that disposable nonreusable electrodes should be properly labeled, "one time use only." The introducer must maintain the sterility of the electrode during introduction and attachment to prevent infection of the fetal scalp. The Panel believes that material standards are necessary to prevent electrode stretching (particularly spiral electrodes) and electrode degradation. The Panel notes that when this device is used with other devices, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its classification recommendation on personal knowledge of, and experience with, the device. Information presented to the Panel indicates that spiral disposable fetal scalp electrodes are the generally accepted modality for direct fetal monitoring (Ref. 1). The Panel also reviewed the literature on the device, citing a representative article, which suggests that the most common complications of use of the fetal scalp electrode are scalp abscess and neonatal sepsis (bacteria in the bloodstream of the newborn) (Ref. 2). The Panel, however, stated that extensive clinical experience (over one million used) in many perinatal centers demonstration its overall safety and effectiveness.

5. Risks to health: (a) Adverse tissue reaction: Material in the device could degrade, or otherwise react, to cause a systemic or local tissue reaction when the device comes in contact with the patient. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (c) Trauma and hemmorrhage: Poor design or incorrect application could cause trauma to the fetal scalp or brain.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that fetal scalp circular (spiral) electrodes (and applicators) be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. In addition to the data presented by the Panel, the Commissioner notes that there is a 0.4 percent incidence of trauma associated with the spiral electrode (Ref. 3), and clinical use of the circular (spiral) electrode has been rapidly learned and accepted (Ref. 5). It has proved reliable and simplifies direct fetal heart rate monitoring (Refs. 3 and 4). A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

FDA's general concerns about fetal monitoring apply to fetal scalp circular (spiral) electrodes and applicators. These concerns are described in proposed § 884.2740 regarding the classification of perinatal monitoring systems published elsewhere in this issue of the **Federal Register.**

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the First Meeting of the Fetal Monitoring Device Subcommittee of the Obstetrical and Gynecological Device Classification Panel, November 1976.

2. Atlas, M. and D. M. Serr, "Hazards of Fetal Scalp Electrodes,", *Lancet*, 1:648, March 1976.

3. Plavidal, F. J. and A. Werch, "Fetal Scalp Abscess Seconday to Intrauterine Monitoring," *American Journal of Obstetrics and Gynecology*, 125:65–70, May, 1976.

4. Paul, R. H. and E. H. Hon, "Clinical Fetal Monitoring: IV, Experience with a Spiral Electrode," *Obstetrics and Gynecology*, 41:777–780, 1973.

5. Ghosh, A. K. and R. H. Lipton, "Fetal Scalp Electrodes," *Lancet* 1:1075, May 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2675 as follows:

§ 884.2675 Fetal scalp circular (spiral) electrode and applicator.

(a) *Identification.* A fetal scalp circular (spiral) electrode and applicator is an obstetrical device used to obtain a fetal electrocardiogram during labor and delivery. It establishes electrical contact between fetal skin and an external monitoring device by a shallow subcutaneous puncture of fetal scalp tissue with a curved needle or needles. This generic type of device includes nonreusable spiral electrodes and reusable circular electrodes.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1130]

[FR Doc. 79–9434 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Fetal Scalp Clip Electrodes and Applicators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fetal scalp clip electrodes and applicators into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of fetal scalp clip electrodes and applicators:

1. Identification: A fetal scalp clip electrode and applicator is a device designed to establish electrical contact between fetal skin and an external monitoring device by means of pinching skin tissue with a nonreusable clip. This device is used to obtain a fetal electrocardiogram. This generic type of device may include a clip electrode applicator. The Panel previously considered this generic type of device under the name "nonreusable fetal scalp clip electrode."

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that fetal scalp clip electrodes and applicators be classified into class III (premarket approval). Because the device is designed to crush the fetal tissue, thus increasing the potential for difficult removal, fetal scalp abscess, and pressure necrosis, the clip electrode presents an unreasonable risk to health. The Panel believes that certain characteristics of the fetal scalp clip electrode could be controlled by performance standards. The device materials contacting fetal or maternal tissue should meet a biocompatibility standard to prevent an adverse tissue reaction. Proper sterilization procedures can prevent infection. When this device is used with other devices, the combination must be compatible. The Panel, however, believes that performance standards alone will not provide reasonable assurance of the safety and effectiveness of this device. The Panel is primarily concerned about the clip and applicator design. The Panel believes that only clinical investigations can demonstrate

that the pressure design of the clip will prevent harmful tissue damage when the clip electrode is applied or removed. The Panel also recommends that disposable, nonreusable clip electrodes be properly labeled as "one time use only." Because the Panel believes that a performance standard cannot provide the necessary assurance of safety and effectiveness, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. Information presented to the Panel indicated a 1 to 2 percent infection rate for newborns on whom fetal scalp clip electrodes were used (Ref. 1). The Panel noted that this device is in limited use in the United States because the circular (spiral) electrode, preferred because it is easier to apply and remove, is available.

5. Risks to health: (a) Adverse tissue reaction: Material in the device could cause a local tissue or systemic reaction when the device comes in contact with the fetus. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (c) Tissue damage: Poor design or incorrect application could result in scalp injury when the device pinches the fetal scalp.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that fetal scalp clip electrodes and applicators be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and has obtained additional information and data describing the application of fetal scalp clip electrodes and applicators to the fetal scalp (Refs. 2, 3, and 4). The literature cites the risk of subsequent infection of the fetus to be 0.34 percent to 0.44 percent of all newborns following fetal scalp clip electrode application. However, the incidence may be considerably higher when fetal monitoring is only occasionally used by inexperienced physicians (Ref. 1). Furthermore, the rarity of such abscesses in full-term newborns who have not been monitored in utero substantiates the Panel's belief that use of this device is associated with an increase in this type of medical complication in newborns.

The Commissioner believes that the device is purported or represented to be for a use (diagnosis of fetal distress) that is of substantial importance in preventing impairment of human health. The Commissioner also believes that the device presents a potential unreasonable risk of illness or injury to the fetus and patient because of the absence of data adequate to assure the safe and effective use of this device. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

FDA's general concerns about fetal monitoring apply to fetal scalp clip electrodes and applicators. These concerns are described in proposed § 884.2740 regarding the classification of perinatal monitoring systems published elsewhere in this issue of the Federal Register.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the First Meeting of the Fetal Monitoring Devices Subcommittee of the Obstetrical and Gynecological Device Classification Panel, November 1976.

2. Cordero, L. and E. H. Hon, "Scalp Abscess: A Rare Complication of Fetal Monitoring," *Journal of Pediatrics*, 78:533–537, March 1971.

3. Plavidal, F. J. and A. Werch, "Fetal Scalp Abscess Secondary to Intrauterine Monitoring," *American Journal of Obstetrics and Gynecology*, 125:65–70, May 1976.

4. Scanlon, J. W. and E. I. Walkley, "Neonatal Blood Loss as a Complication of Fetal Monitoring," *Pediatrics*, 50:934–936, 1972.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2685 as follows:

§ 884.2685 Fetal scalp clip electrode and applicator.

(a) *Identification.* A fetal scalp clip electrode and applicator is a device designed to establish electrical contact between fetal skin and an external monitoring device by means of pinching skin tissue with a nonreusable clip. This device is used to obtain a fetal electrocardiogram. This generic type of device may include a clip electrode applicator.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1131]

[FR Doc. 79–9435 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Intrauterine Pressure Monitors and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intrauterine pressure monitors and accessories into class II (performance standards). The FDA is also publishing the recommendation of the of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of intruaterine pressure monitors and accessories:

1. Identification: An intrauterine pressure monitor is a device designed to detect and measure intrauterine and amniotic fluid pressure with a catheter placed transcervically into the uterine cavity. The device is used to monitor the strength, duration, and frequency of uterine contractions during labor. This generic type of device includes the following accessories: signal analysis and display equipment, patient and equipment supports, and component parts. The Panel includes in this generic type of device those devices identified as "intrauterine pressure recorder," "intrauterine catheter (and introducer)," and "intrauterine pressure transducer."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the intrauterine pressure monitor and accessories be classified into calss II (performance standards) because the Panel believes that device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. Electrical safety standards are required to minimize the hazards of electrical shock. The catheter material must be strong enough to prevent its tip from breaking. Material standards are necessary to assure the appropriate flexibility of the intrauterine catheter so it can easily be introduced into the uterus and will not perforate the uterus. The Panel believes that measurement standards are necessary to assure an accurate indication of the strength, duration, and frequency of uterine contractions. The Panel recommends standardizing the distance from the catheter to the pressure holes to permit proper catheter tip placement. A calibrated pressure hole size will prevent inaccurate pressure measurement. The Panel also recommends that the catheter have depth markings along its side so one can determine how far the catheter is inserted and if a part has broken off when it is removed. The Panel also notes that when this device is used with other devices, the combination must be compatible. The method of sterilization must be stated in the device labeling to prevent infection.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device (Ref. 1). The Panel also reviewed the literature on the device and cited an unusual complication of this type of monitoring—a broken catheter tip (Ref. 2). Extensive clinical experience, which includes more than 1 million uses over the past several years (Ref. 3) in many perinatal centers, establishes the overall safety of the procedure and of the device.

5. Risks to health: (a) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (b) Misdiagnosis: Inadequate design or calibration could lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment which places the patient or fetus at risk unnecessarily. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient or fetus. (d) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (e) Trauma: Improper depth or placement or breakage of the catheter could cause the device to puncture the patient's uterus.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that intrauterine pressure monitors and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

FDA's general concerns about fetal monitoring apply to intrauterine pressure monitors and accessories. These concerns are described in proposed § 884.2740 regarding the classification of perinatal monitoring systems published elsewhere in this issue of the **Federal Register**.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the First Meeting of the Fetal Monitoring Device Subcommittee of the Obstetrical and Gynecological Device Classification Panel, November 1976.

2. Okada, D. M. and C. J. Hobel, "Unusual Complication of Fetal Monitoring: a Broken Intrauterine Catheter Tip," *American Journal of Obstetrics and Gynecology*, 117:1147–1148, December 1973.

3. Newman, M. R., "Fetal Monitoring Techniques," *CRC Critical Reviews in Bioengineering*, 2(2):139–140, January 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2700 as follows:

§ 884.2700 Intrauterine pressure monitor and accessories.

(a) *Identification.* An intrauterine pressure monitor is a device designed to detect and measure intrauterine and amniotic fluid pressure with a catheter placed transcervically into the uterine cavity. The device is used to monitor the strength, duration, and frequency of uterine contractions during labor. This generic type of device includes the following accessories: signal analysis and display equipment, patient and equipment supports, and component parts.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Receivd comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1132]

[FR Doc. 79–9436 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of External Uterine Contraction Monitors and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external uterine contraction monitors and accessories into class II

(performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of external uterine contraction monitors:

1. Identification: An external uterine contraction monitor is a device used to monitor the progress of labor. It measures the strength, duration, and frequency of uterine contractions with a transducer strapped to the maternal abdomen. This generic type of device may include external pressure transducer, support straps, and other patient and equipment supports. The Panel previously considered this generic type of device under the name "tokodynamometer."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that external uterine contraction monitors be classified into class II (performance standards) because the Panel believes that measurement standards are necessary to assure an accurate indication of the strength, duration, and frequency of uterine contractions. A design standard or appropriate labeling is required to prevent excessive tightening of the strap so as to constrict circulation. A material standard is necessary to assure that the strap surface is smooth and will not cause trauma to the patient. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device. A review of the literature on the device shows that the continuous monitoring of labor identifies abnormal uterine contractions, provides a guide for regulation of oxytocin infusion (used to induce or shorten labor), and promotes the management of abnormal labor (Ref. 1). The Panel noted that extensive clinical use (over 5 million uses) in hospitals and medical centers demonstrates the safety of this device.

5. Risks to health: (a) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (b) Misdiagnosis. Inadequate design of the device can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient or fetus at risk unnecessarily. (c) Trauma: Surface roughness or structure of the device could result in the device injuring the patient by constricting circulation and applying excessive pressure to the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that external uterine contraction monitors be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

FDA's general concerns about fetal monitoring apply to external uterine contraction monitors and accessories. These concerns are described in proposed § 884.2740 regarding the classification of perinatal monitoring systems published elsewhere in this issue of the **Federal Register**.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. LaCroi, G. E., "Monitoring Labor by an External Tokodynamometer," *American Journal of Obstetrics and Gynecology*, 101:111–119, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2720 as follows:

§ 884.2720 External uterine contraction monitor and accessories.

(a) *Identification.* An external uterine contraction monitor is a device used to monitor the progress of labor. It measures the strength, duration, and frequency of uterine contractions with a transducer strapped to the maternal abdomen. This generic type of device may include an external pressure transducer, support straps, and other patient and equipment supports.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1133]

[FR Doc. 79–9437 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Perinatal Monitoring Systems and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying perinatal monitoring systems

and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of perinatal monitoring systems and accessories:

1. Identifications: A perinatal monitoring system is a device used to show graphically the relationship between maternal labor and the fetal heart rate by means of combining and coordinating uterine contraction and fetal heart monitors with appropriate displays. It is used to assist in the assessment of the well-being of mother and fetus during pregnancy, labor, and delivery. This generic type of device may include any of the devices subject to six other proposals (§§ 884.2600, 884.2640, 884.2660, 884.2675, 884.2700, and 884.2720) published in this issue of the **Federal Register.** This generic type of device also includes the following accessories: central monitoring system and remote repeaters, signal analysis and display equipment, patient and equipment supports, and component parts. The Panel previously considered this generic type of device under the name "perinatal monitoring complex."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that perinatal monitoring systems and accessories be classified into class II (performance standards) because the Panel believes that standards are necessary to assure that the device effectively indicates the progress of labor and its effect upon the fetus. The Panel believes that perinatal monitoring systems must meet certain measurement requirements to ensure that they produce signals corresponding to the physiological condition. Also, electrical safety standards are necessary to minimize the hazards of electrical shock. The Panel further believes that if the device incorporates ultrasonic monitors, these monitors must not emit ultrasound energy at radiation levels unsafe to the patient or fetus. The Panel notes that when this device is used with other devices as a system, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also recommends that the accuracy, reproducibility, and limitations of the device's measurements be stated in the labeling. The Panel initially recommended that the device be classified into class III (premarket approval) because long-term effects of diagnostic ultrasonic are not known. The Panel changed its recommendation for diagnostic ultrasonic devices from class III to class II after considering the benefits and risks from the use of these devices, and the available data. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on an extensive review of the data presented to the Panel and to the Biologic Effects of Ultrasound Subcommittee (BEUS) (Ref. 1). These data, in conjuction with the extensive experience of some Panel members, reveal no observable damage to tissue occurring at power levels below 100 milliwatts per square centimeter (spatial peak, temporal average) of ultrasonic energy with a time exposure normal for diagnostic purposes. This conclusion has been published in a statement of the American Institute of Ultrasound in Medicine (AIUM) (Ref. 2). To the Panel's knowledge, no currently marketed device exceeds that power limit. Furthermore, a followup of children exposed to diagnostic doses in the womb shows no evidence of deleterious effects of ultrasound (Ref. 1). However, the Panel does recommend that fetal exposure (duration, area, and output intensity) should be minimized (consistent with obtaining necessary clinical information) because optimum power levels, maximum exposure times, and long-term effects upon the fetus from routine clinical use are unknown at this time. A technical committee chairman from the National Electrical Manufacturer's Association (NEMA) presented a proposal for diagnostic ultrasonic equipment parameters to the BEUS (Ref. 3). The Panel recommends that the NEMA maximum allowable values of ultrasonic energy and parameters suggested for the labeling of ultrasonic devices be used as an interim guideline for developing a performance standard for obstetric and abdominal diagnostic ultrasonic devices.

5. Risks to health: (a) Tissue damage: A device that uses ultrasonic energy may produce tissue damage if the energy output is not controlled. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Misdiagnosis: Inadequate design or calibration could lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (d) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that perinatal monitoring systems and accessories be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation and has obtained other data and information describing fetal monitoring. Combining uterine contraction and fetal heart rate monitors is a well-understood mode. Guidelines for fetal monitoring, including terminology, indications, evaluation, and instrumentation, have been established (Refs. 8 and 9). This device is commonly called a fetal monitor, but the Commissioner considers this name too general for regulatory purposes.

In its report, the Panel explicitly addressed only the ultrasonic monitoring aspects of this device. However, the concerns described in the six related fetal or uterine monitoring classification proposals (§§ 884.2600, 884.2640, 884.2660, 884.2675, 884.2700, and 884.2720) published elsewhere in this issue of the **Federal Register** apply to perinatal monitoring systems that include devices subject to these proposals. Furthermore, perinatal monitoring systems and accessories which include any of the devices subject to these proposals, must comply with any regulations that apply to any of their constituent parts.

Stratmeyer's review (Ref. 4) of the possible biological effects of ultrasound includes references to investigations showing that exposures of ultrasonic energy similar to those used in perinatal monitoring systems may cause biological effects in laboratory animals. Although those investigations are cause

for concern, the Commissioner regards them as inconclusive at this time. The studies have yet to be verified, and some investigators question the methods or findings of these investigations or their applicability to humans.

The Biological Effects of Ultrasound Subcommittee of FDA's Obstetrical and Gynecological Device Classification Panel has reviewed the possible adverse effects of diagnostic ultrasound devices. (The Subcommittee was established because of FDA's special concerns about the obstetrical use of ultrasound, based upon several studies involving laboratory animals that showed various biological effects from prenatal ultrasound exposures (Ref. 4).) The Subcommittee concluded that there is sufficient information available to establish a standard for diagnostic ultrasound devices generally (Refs. 5, 6, and 7).

In the **Federal Register** of February 13, 1979 (44 FR 9542), FDA published a notice of intent in the **Federal Register** announcing that it is considering an action program to reduce exposure to diagnostic ultrasound as much as practicable, consistent with the need for essential diagnostic information. One action the agency is considering is promulgation of a performance standard under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602, 42 U.S.C. 2636 et seq.).

The agency believes that a performance standard under the Radiation Control for Health and Safety Act may be necessary for perinatal monitoring systems and accessories because general controls by themselves may be insufficient to control the risks to health. The agency also believes that there is sufficient information to establish a standard that will provide reasonable assurance of the safety and effectiveness of the device.

FDA recognizes that some scientists believe that the effectiveness of electronic fetal monitoring has not been thoroughly evaluated and, therefore, that benefits should not be presumed (Refs. 9 and 10). A recent study shows that electronic fetal monitoring saves many fetal lives when used in high-risk pregnancies but is of negligible value when used in low-risk pregnancies, which are by far the most numerous (Refs. 8 and 11). Electronic fetal monitoring also appears to result in increased caesarian deliveries without a resulting improvement in outcome (Ref. 9). Also, monitoring results in decreased maternal mobility, which can cause ominous readings and complications (Refs. 12 and 13). Although internal monitors are more accurate, their use requires rupture of the amniotic sac, which increases the risk of infection and of unusually strong contractions and which compels completion of the birth within a short time (Ref. 10). Therefore, the choice of electronic fetal monitoring by the patient and the medical practitioner must be made in light of the associated risk. Despite doubts about the value of universal fetal monitoring, the value of monitoring in certain cases is clear. Moreover, perinatal monitoring systems have matured to the extent that standards can be written for their technical performance. In fact, guidelines for fetal monitoring, including terminology, indications, evaluation, and instrumentation, have been established (Refs. 14 and 15).

The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Nyborg, W. L., "Minimum Thresholds for Bio-Effects of Ultrasound," Unpublished paper, Attachment E to Summary Minutes of the First Meeting of the Biologic Effects of Ultrasound Subcommittee, Panel on review of Obstetrical-Gynecological Devices, January 1978.

Bio-Effects committee, "AIUM Committee Report," *Reflections, 3(1):18, 1977.*

3. Buxbaum, C., "Diagnostic Ultrasonic Equipment Parameters: Recommendations of the Technical Committee, Ultrasound Section, NEMA, October 22, 1976," Unpublished paper, Attachment E to Obstetrical and gynecological Device Panel Classification Report, November 1977.

4. Stratmeyer, M. E., "Research Directions in Ultrasound Bioeffects—A Public Health View," Symposium on Biological Effects and Characterizations of Ultrasound Sources, June 2 and 3, 1977, pp. 240–245, HEW Publication (FDA) 78–8048.

5. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (First Meeting), Jan. 22–23, 1976.

6. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (Second Meeting), Oct. 28, 1976.

7. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (Third Meeting), Oct. 4, 1977.

8. Summary Minutes of the Fetal Monitoring Device Subcommittee of the Obstetrical and Gynecological Device Classification Panel, November 1976.

9. Haverkamp, A. D., H. F. Thompson, J. G. McFee, and C. Cetrulo, "The Evaluation of Continuous Fetal Heart Rate Monitoring in High-Risk Pregnancy," *American Journal of Obstetrics and Gynecology, 125:310–320, June 1976.*

10. Auld, P., "Adverse Effects of Invasive and Non-Invasive Fetal Monitoring," Unpublished paper, Attachment 3 to Summary Minutes of the Fetal Monitoring Devices Subcommittee of the Obstetrical and Gynecological Device Classification Panel, November 1976.

11. Neutra, R. R., S. E. Feinberg, S. Greenland, and E. A. Friedman, "Effect of Fetal Monitoring on Neonatal Death Rates," *New England Journal of Medicine,* 299:324–326, Augst 1978.

12. Bardon, T., "The Current Status of Invasive Fetal Monitors," Unpublished paper, Attachment 2 to Summary Minutes of the Fetal Monitoring Devices Subcommittee of the Obstetrical and Gynecological Device Classification Panel, November 1976.

13. Baker, R. A., "Editorial: Technologic Intervention in Obstetrics," *Obstetrics and Gynecology,* 51:241–243, February 1978.

14. ACOG Technical Bulletin Number 32, "Fetal Heart Rate Monitoring: Guidelines for Monitoring, Terminology, and Instrumentation," American College of Obstetricians and Gynecologists, Chicago, IL, June 1975.

15. ACOG Technical Bulletin Number 44, "Intrapartum Fetal Monitoring," American College of Obstetricians and Gynecologists, Chicago, IL, January 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2740 as follows:

§ 884.2740 Perinatal monitoring system and accessories.

(a) *Identification.* A perinatal monitoring system is a device used to show graphically the relationship between maternal labor and the fetal heart rate by means of combining and coordinating uterine contraction and fetal heart monitors with appropriate displays. It is used to assist in the assessment of the well-being of mother and fetus during pregnancy, labor, and delivery. This generic type of device may include any of the devices subject to six other preceding sections (§§ 884.2600, 884.2640, 884.2660, 884.2675, 884.2700, and 884.2720). This generic type of device includes the following accessories: central monitoring system and remote repeaters, signal analysis

and display equipment, patient and equipment supports, and component parts.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1134]

[FR Doc. 79–9438 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Fetal Stethoscopes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fetal stepthoscopes into class I (general controls). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of fetal stethoscopes:

1. Identification: A fetal stethoscope is a device used for listening to fetal heart sounds. It is designed to transmit the fetal heart sounds not only through sound channels by air conduction but also through the user's head by tissue conduction into the user's ears. It does not use ultrasonic energy. This device is designed to eliminate noise interference commonly caused by handling conventional stethoscopes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that fetal stethoscopes by classified into class I because it is a simple and safe device whose effectiveness can easily be determined. General controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device. The fetal stethoscope has been in use for many years.

5. Risks to health: None identified.

Proposed classification

The Commissioner agrees with the Panel recommendation and is proposing that fetal stethoscopes be classified into class I (general controls) with no exemptions because the Commissioner believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2900 as follows:

§ 884.2900 Fetal stethoscope.

(a) *Identification.* The fetal stethoscope is a device used for listening to fetal heart sounds. It is designed to transmit the fetal heart sounds not only through sound channels by air conduction, but also through the user's head by issue conduction into the user's ears. It does not use ultrasonic energy. This device is designed to eliminate noise interference commonly caused by handling conventional stethoscopes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1135]

[FR Doc. 79–9439 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Obstetric Ultrasonic Transducers and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying obstetric ultrasonic transducers and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–

65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of obstetric ultrasonic transducers and accessories:

1. Identification: An obstetric ultrasonic transducer is a device used to apply ultrasonic energy to, and receive ultrasonic energy from, the body in conjunction with an obstetric monitor or imager. The device converts electrical signals into ultrasonic energy, and vice versa, by means of an assembly distinct from an ultrasonic generator. This generic type of device includes the following accessories: coupling gel, preamplifiers, amplifiers, signal conditioners with their power supply, connecting cables, and component parts. This generic type of device does not include devices used to generate the ultrasonic frequency electrical signals for application. The Panel previously considered this generic type of device under the name "ob-gyn ultrasonic transducer."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device is a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the obstetric ultrasonic transducer and accessories be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure that the emitted ultrasonic energy does not reach levels of radiation unsafe to the patient or fetus. The Panel believes that device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel also believes that electrical safety standards are required to minimize the hazards of electrical shock. The Panel notes that when this device is used with other devices as a system, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel weighed the benefit to risk factor of the use of diagnostic ultrasound with the available data, recognizing that the long-term effects of diagnostic ultrasound are not well known. The Panel initially recommended that the device be classified into class III (premarket approval) because the long-term effects of diagnostic ultrasound are not known. The Panel changed its recommendation for diagnostic ultrasound devices from class III to class II after considering the benefits and risks from the use of these devices, and the available data. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on an extensive review of the data on ultrasonic devices presented to the Panel and to the Biologic Effects of Ultrasound Subcommittee (BEUS) (Ref. 1). These data, in conjunction with the extensive experience of some Panel members, supported the conclusion that there is no observable damage to tissue when the transducer power output is below 100 milliwatts per square centimeter (spatial peak, temporal average) of ultrasonic energy within a normal diagnostic exposure time. This conclusion has been published in a statement of the American Institute of Ultrasound in Medicine (AIUM) (Ref. 2.). To the Panel's knowledge, no currently marketed device exceeds that power limit. Furthermore, a followup of children exposed to diagnostic doses in the womb showed no evidence of deleterious effects (Ref. 1). However, the Panel does recommend that fetal exposure (duration, area, and output intensity) should be minimized (consistent with obtaining necessary clinical information) because optimum power levels, maximum exposure times, and long-term effects upon the fetus from routine clinical use are unknown at this time. A technical committee chairman from the National Electrical Manufacturers Association (NEMA) presented a proposal for diagnostic ultrasonic equipment parameters to the BEUS (Ref. 3). The Panel recommends that the NEMA maximum allowable values of ultrasonic energy and parameters suggested for the labeling of ultrasonic devices be used as an interim guideline for developing a performance guideline for obstetric and abdominal diagnostic ultrasonic devices.

5. Risks to health: (a) Tissue damage: The device's ultrasonic energy may cause tissue damage if the energy output is not controlled. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Adverse tissue reaction: Material in or substances used with the device could result in a systemic or local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that obstetric ultrasonic transducers and accessories be classified into class II (performance standards). Stratmeyer's review (Ref. 4) of the possible biological effects of ultrasound includes references to investigations showing that exposures of ultrasonic energy similar to those used in obstetrical, gynecological, and abdominal diagnosis may cause biological effects in laboratory animals. Although those investigations are cause for concern, the Commissioner regards them as inconclusive at this time. The studies have yet to be verified, and some investigators question the methods or findings of these investigations or their applicability to humans.

The Biological Effects of Ultrasound Subcommittee of FDA's Obstetrical and Gynecological Device Classification Panel has reviewed the possible adverse effects of diagnostic ultrasound devices. (The Subcommittee was established because of FDA's special concerns about the obstetrical use of ultrasound, based upon several studies involving laboratory animals that showed various bilogical effects from prenatal ultrasound exposures (Ref. 4).) The Subcommittee concluded that there is sufficient information available to establish a standard for diagnostic ultrasound devices generally (Refs. 5, 6, and 7).

In the **Federal Register** of February 13, 1979 (44 FR 9542), FDA published a notice of intent in the **Federal Register** announcing that it is considering an action program to reduce exposure to diagnostic ultrasound as much as practicable, consistent with the need for essential diagnostic information. One action the agency is considering is promulgation of a performance standard under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602, 42 U.S.C. 2636 et seq.).

The agency believes that a performance standard under the Radiation Control for Health and Safety Act may be necessary for obstetric ultrasonic transducers and accessories because general controls by themselves may be insufficient to control the risks to health. The agency also believes that there is sufficient information to establish a standard that will provide reasonable assurance of the safety and effectiveness of the device.

FDA's general concerns about fetal monitoring apply to obstetric ultrasonic transducers and accessories used in fetal monitoring. These concerns are described in proposed § 884.2740 regarding the classification of perinatal monitoring systems published elsewhere in this issue of the **Federal Register.**

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Nyborg, W. L., "Minimum Thresholds for Bio-Effects of Ultrasound," Unpublished paper, Attachment E to Summary Minutes of

the First Meeting of the Biologic Effects of Ultrasound Subcommittee, Panel on Review of Obstetrical-Gynecological Devices, January 1976.

2. Bio-Effects Committee, "AIUM Committee Report," *Reflections* 3(1):18, 1977.

3. Buxbaum, C., "Diagnostic Ultrasonic Equipment Parameters: Recommendations of the Technical Committee***October 22, 1976," Unpublished paper, Attachment E to Obstetrical and Gynecological Device Panel Classification Report, November 1977.

4. Stratmeyer, M. E., "Research Directions in Ultrasound Bioeffects—A Public Health View," Symposium on Biological Effects and Characterizations of Ultrasound Sources, June 2 and 3, 1977, pp. 240–245, HEW Publication (FDA) 78–8048.

5. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (First Meeting), Jan. 22–23, 1976.

6. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (Second Meeting), Oct. 28, 1976.

7. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (Third Meeting), Oct. 4, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.2960 as follows:

§ 884.2960 Obstetric ultrasonic transducer and accessories.

(a) *Identification.* An obstetric ultrasonic transducer is a device used to apply ultrasonic energy to, and to receive ultrasonic energy from, the body in conjunction with an obstetric monitor or imager. The device converts electrical signals into ultrasonic energy, and vice versa, by means of an assembly distinct from an ultrasonic generator. This generic type of device includes the following accessories: coupling gel, preamplifiers, amplifiers, signal conditioners with their power supply, connecting cables, and component parts. This generic type of device does not include devices used to generate the ultrasonic frequency electrical signals for application.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1136]

[FR Doc. 79–9440 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Cervical Drains

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cervical drains into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal eleswhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cervical drains:

1. Identification: A cervical drain is a device designed to provide an exit channel for draining discharge from the cervix after pelvic surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cervical drains be classified into class II (performance standards) because the Panel believes that since device materials contacting the cervix could degrade and cause an adverse tissue reaction, they should therefore meet a biocompatibility standard. The Panel states that, because this device presents an open channel to the uterus, infection might occur. The Panel recommends that the method of sterilization be stated in the device labeling to prevent infection. The Panel also believes that material standards are necessary to assure appropriate hardness and flexibility of the device to prevent collapse of the drain. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device.

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Adverse tissue reaction: Material or substances in the device could result in a systemic or local tissue reaction when the device comes in contact with the patient. (c) Loss of patency: Use of inappropriate material could allow the device to collapse, causing a restriction in the flow of discharge.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that cervical drains be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority

delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 by adding new Subpart D and § 884.3200 as follows:

Subpart D—Obstetrical and Gynecological Prosthetic Devices

§ 884.3200 Cervical drain.

(a) *Identification.* A cervical drain is a device designed to provide an exit channel for draining discharge from the cervix after pelvic surgery.

(b) *Classification.* Class III (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1137]

[FR Doc. 79–9441 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03

[21 CFR Part 884]

Classification of Vaginal Pessary

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying the vaginal pessary into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of the vaginal pessary:

1. Identification: A vaginal pessary is a removable structure placed in the vagina to support the pelvic organs and is used to treat such conditions as uterine prolapse (falling down of uterus), uterine retroposition (backward displacement), or gynecologic hernia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the vaginal pessary be classified into class II (performance standards) because the Panel believes that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel also believes that design standards are necessary to assure that the device's shape does not cause urethral or bowel obstruction. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also recommends that proper cleaning procedures and the method of use be stated in the device labeling to prevent infection or injury to surrounding organs. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The need for proper fit and cleaning is emphasized in many standard textbooks on gynecology (Refs. 1, 2, and 3).

5. Risks to health: (a) Infection: If the device is not properly cleaned, it may introduce microorganisms that could cause infection. (b) Trauma: Structural failure of the device could cause the device to injure the patient's vagina, cervix, or uterus. (c) Adverse tissue reaction: Material or substances in the device could result in a systemic or local tissue reaction when the device contacts the patient's vagina. (d) Urethral or bowel obstruction: Poor design of the vaginal pessary shape could cause urethral or bowel obstruction.

Proposed classification

The Commissioner agrees with the Panel recommendation and is proposing that the vaginal pessary be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

The Commissioner points out that the vaginal pesary differs from the stem-type and wing-type pessaries declared misbranded in § 801.408 (21 CFR 801.408). The stem-type or wing-type pessary is an intracervical device that is inserted into the cervical canal and is used to prevent pregnancy.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305) (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Greenhill, J. P., "Office Gynecology," 9th Ed., Yearbook Medical Publishers, Inc., Chicago, IL, 1971.

2. Novak, E. R., et al., "Novak's Textbook of Gynecology," 9th Ed., Baltimore, MD, Williams and Wilkins Co., 1975.

3. Benson, R. C., Current Obstetric and Gynecologic Diagnosis and Treatment, Los Altos, CA, Lange Medical Publications, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart D by adding new § 884.3575 as follows:

§ 884.3575 Vaginal pessary.

(a) *Identification.* A vaginal pessary is a removable structure placed in the vagina to support the pelvic organs and is used to treat such conditions as uterine prolapse (falling down of uterus), uterine retroposition (backward displacement), or gynecologic herina.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1138]

[FR Doc. 79–9442 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Fallopian Tube Prostheses

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fallopian tube prostheses into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–395), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of fallopian tube prostheses:

1. Identification: A fallopian tube prostheses is a device designed to maintain the patency (openness) of the fallopian tube and is used after reconstructive surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that fallopian tube prosthesis be classified into class II (performance standards) because the Panel believes that since device materials contacting the body could degrade and cause an adverse tissue reaction, they should therefore meet a biocompatibility standard. Because of the reported risk of breakage and loss of the device within the body, the Panel recommends that it be radiopaque to facilitate location by radiography. The Panel recommends that the method of sterilization be stated in the device labeling, to prevent infection. The Panel believes that general controls alone will not provide sufficient control of these characteristics. The Panel also believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel also reviewed the literature on fallopian tube prostheses. Most patients in whom this prosthesis was used maintained tubal patency, and some patients subsequently conceived (Ref. 1).

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Trauma, hemorrhage, perforation: Breakage of the device could result in its injuring or puncturing the patient's bowel or other peritoneal organs. (c) Adverse tissue reaction: Material or substances in the device could result in a systemic or local tissue reaction when the device comes in contact with the patient's tissues.

Proposed classification

The Commissioner agrees with the Panel recommendation and is proposing that fallopian tube prostheses be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation and has obtained additional data and information describing the application of fallopian tube prostheses. This prosthesis is not considered an implant for purposes of the classification procedures regulation § 860.3(d) (21 CFR 860.3(d)) because it is used to maintain patency of the fallopian tube after reconstructive surgery for periods of less than 30 days (Ref. 2), and because the Commissioner has determined that the device need not be considered an implant to protect human health. The classification procedures regulation was published in the **Federal Register** of July 28, 1978 (43 FR 32988). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Roland, M. and D. Leisten, "Tuboplasty in 130 Patients: Improved Results Due to Stents and Preoperative Endoscopy," *Obstetrics and Gynecology*, 39:57–64, 1972.

2. Rigney, B.F., "Case Report: Mechanical Failure of a Spiral Transabdominal Teflon Stent in Tuboplasty," *Fertility and Sterility*, 26:186–189, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart D by adding new § 884.3650 as follows:

§ 884.3650 Fallopian tube prosthesis.

(a) *Identification.* A fallopian tube prosthesis is a device designed to maintain the patency (openness) of the fallopian tube and is used after reconstructive surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may

submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs

Docket No. 78N-1140
[FR Doc. 79-9443 Filed 4-2-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Vaginal Stents

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vaginal stents into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation regarding classification of vaginal stents:

1. Identification: A vaginal stent is a vaginal-shaped device designed to fill the vaginal cavity. This device is used to enlarge the vagina by stretching or to support the vagina after reconstructive surgery. The panel includes in this generic type of device "vaginal molds" and "vaginal dilators."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

Summary of reasons for recommendation: The Panel recommends that vaginal stents be classified into class II (performance standards) because the Panel believes that materials contacting the vagina should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel also believes that material standards are necessary to assure an adequate surface finish to prevent laceration of the vagina. The Panel recommends that the method of sterilization be stated in the device labeling to prevent infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device.

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Trauma: Rough surface finish of the device could injure the patient's vagina. (c) Adverse tissue reaction: Material or substances in the device could result in a systemic or local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that vaginal stents be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation and has obtained other data and information describing the application of the vaginal stent. This device is not considered an implant for purposes of the classification procedures regulation § 860.3(d) (21 CFR 860.3(d)) because it is put in place after reconstructive surgery for periods of less than 30 days (Refs. 1 and 2), and because the Commissioner has determined that the device need not be considered an implant to protect human health. The classification procedures regulation was published in the Federal Register of July 28, 1978 (43 FR 32988). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Watring, W. G., L. D. Lagass, M. L. Smith, G. H. Johnson, et al., "Vaginal Reconstruction Following Extensive Treatment for Pelvic Cancer," *American Journal of Obstetrics and Gynecology*, 125(6):809-814, July 1976.

2. Jones, Jr., H. W. and M. E. Andrews, "Surgery for Congenital Anomalies of the Uterus and Vagina and for Infertility," *in* "Gynecologic Surgery: Errors, Safeguards, Salvage." Edited by Ridley, J. H., The Williams and Wilkins Co., Baltimore, pp. 202-215, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart D by adding new § 884.3900 as follows:

§ 884.3900 Vaginal stent.

(a) *Identification.* A vaginal stent is a vaginal-shaped device designed to fill the vaginal cavity. This device is used to enlarge the vagina by stretching or to support the vagina after reconstructive surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N-1141]
[FR Doc. 79-9444 Filed 4-2-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Endoscopic Electrocautery and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying the endoscopic electrocautery and accessories into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classified Panel, an FDA advisory committee, made the following recommendation regarding the classification of the endoscopic electrocautery and accessories:

1. Identification: An endoscopic electrocautery is a device used to perform female sterilization under endoscopic observation. It is designed to coagulate fallopian tubes with a probe heated by low-voltage energy. This generic type of device includes the following accessories: electrical generators, probes, and electrical cables. The Panel considered this generic type of device under the name "low voltage thermal coagulator and accessories."

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the endoscopic electrocautery be classified into class III (premarket approval) because satisfactory performance has not been sufficiently documented. The Panel believes that it is not possible now to establish an adequate performance standard for this device. The Panel also believes that the insulation and proper heat generation of the endoscopic electrocautery must be controlled to prevent unintended burns. The Panel noted that when this device is used with other devices as a system, the combination must be compatible. The Panel believes that a performance standard will not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a standard to provide such assurance. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based on its recommendation on personal knowledge of, and experience with, the device. The data available show that, although this device appears to be safer than all other types of electrosurgical devices, its effectiveness and the rate of subsequent pregnancies have not yet been determined. A reported study of this device with 200 patients shows enhanced inherent safety features and effective tissue coagulation of the fallopian tubes as assessed by gross and microscopic methods. Sixty-four patients followed from 12 to 21 months show no method failures (Ref. 1).

5. Risks to health: (a) Ectopic (extra-uterine) or contraindicated pregnancy: Poor design of this device could prevent proper fallopian tube coagulation, thus permitting undesired pregnancy or possibly life-threatening ectopic pregnancy. (b) Burns: Poor insulation could cause unintended tissue burns when the device comes in contact with the patient. (c) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that the endoscopic electrocautery and accessories be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and has obtained additional data and information describing the application of the endoscopic electrocautery and accessories. Some of the literature indicates that this device is safe and effective for female sterilization (Ref. 2), but adequate long-term followup data are needed (Ref. 3).

The Commissioner believes that the device is purported or represented to be for a use (female sterilization) that is of substantial importance in preventing impairment of human health. The Commissioner believes that the device presents a potential unreasonable risk of illness or injury because its failure to operate properly could permit a life-threatening ectopic pregnancy. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gunning, J. E., J. P. Tomasula, and T. Garite, "Clinical Experiences Utilizing Thermal Coagulation for Laparascopic Tubal Sterilization," unpublished paper, Attachment 1 to Summary Minutes of the Third Meeting of the Endoscopic and Electrosurgical Device Subcommittee of the Obstetric and Gynecologic Classification Panel, June 1977.

2. Semm, K., "Endocoagulation: A New Field of Endoscopic Surgery," *The Journal of Reproductive Medicine,* 16:195-203, 1976.

3. Wortman, J., "Tubal Sterilization—Review of Methods," *Population Reports,* Series C:73-95, May 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 by adding new Subpart E and § 884.4100 to read as follows:

Subpart E—Obstetrical and Gynecological Surgical Devices

§ 884.4100 Indoscopic electrocautery and accessories.

(a) *Identification.* An endoscopic electrocautery is a device used to perform female sterilization under

endoscopic observation. It is designed to coagulate fallopian tube tissue with a probe heated by low-voltage energy. This generic type of device includes the following accessories: electrical generators, probes, and electrical cables.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs

[Docket No. 78N–1142]

[FR Doc. 79–9445 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Gynecologic Electrocautery and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying the gynecologic electrocautery and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gynecologic electrocautery and accessories:

1. Identification: A gynecologic electrocautery is a device designed to destroy tissue with high temperatures by tissue contact with an electrically heated probe. It is used to excise cervical lesions, perform biopsies, or treat chronic cervicitis under direct visual observation. This generic type of device includes the following accessories: an electrical generator, a probe, and electrical cables. The Panel previous considered this generic type of device under the name "cervical electrocautery and accessories."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the gynecologic electrocautery and accessories be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure that the device's thermal features (heat generation, insulation, and probe tip dimensions) are controlled to prevent unintended burns. The Panel also believes that the device materials contacting the body should meet a biocompatibility standard to prevent adverse tissue reaction. Electrical safety standards are required to minimize the hazards of electrical shock. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The gynecologic electrocautery is used widely, and its indications and hazards are well documented (Ref. 1).

5. Risks to health: (a) Burns: Poor design or incorrect application of the device could result in tissue burns when the device contacts the patient's vulva, vagina, or cervix. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient.

(c) Adverse tissue reaction: Materials or substances in the device could result in a systemic or local tissue reaction when the device comes in contact with the patient. (d) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that the gynecologic electrocautery and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Greenhill, J. P., "Office Gynecology," 9th Ed., Year Book Medical Publisher, Chicago, IL, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart C by adding new § 884.4120 as follows:

§ 884.4120 Gynecologic electrocautery and accessories.

(a) *Identification.* A gynecologic electrocautery is a device designed to destroy tissue with high termperatures by tissue contact with an electrically heated probe. It is used to excise cervical lesions, perform biopsies, or treat chronic cervicitis under direct visual observation. This generic type of device includes the following accessories: an electrical generator, a probe, and electrical cables.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug

Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1143]

[FR Doc. 79–9446 Filed 4–2–79; 8:45 am]
BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Bipolar Endoscopic Coagulator-Cutters and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying bipolar endoscopic coagulator-cutters and accessories into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of bipolar endoscopic coagulator-cutters and accessories:

1. Identification: A bipolar endoscopic coagulator-cutter is a device used to perform female sterilization and other operative procedures under endoscopic observation. It destroys tissue with high temperatures by directing a high frequency electrical current through tissue between two electrical contacts of a probe. This generic type of device includes the following accessories: An electrical generator, probes, and electrical cables. The Panel considered this generic type of device under the name "bipolar laparoscopic coagulator and accessories."

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that bipolar endoscopic coagulator-cutters and accessories be classified into class III. The Panel believes that it is not possible to establish an adequate performance standard for this device because satisfactory performance has not been sufficiently documented. The device is designed to coagulate the fallopian tubes to prevent pregnancy. Due to improper design, however, the device may not adequately coagulate the fallopian tubes. Until the device has been shown to be effective, it must be regulated under strict controls. The Panel believes that a performance standard will not provide reasonable assurance of the safety and effectiveness of the device and that there is insufficient information to establish a standard to provide such assurance. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on its personal knowledge of, and experience with, the device. Data presented to the Panel (Refs. 1 and 2) demonstrate that the bipolar endoscopic coagulator-cutter is perhaps safer than the unipolar endoscopic coagulator-cutter; however, only a limited number of case studies are available. The Panel stated that the data are inadequate at the present time to prove overall long-term effectiveness in tubal sterilization by the bipolar endoscopic coagulator-cutter.

5. Risks to health: (a) Ectopic (extrauterine) or contraindicated pregnancy: Poor design of the two probe electrodes could inhibit proper fallopian tube coagulation with undesired and possibly life-threatening ectopic pregnancy as a consequence. (b) Electrical shock and burns: Although the design of the active probe greatly reduces the hazards of electrical shock and burns, malfunction of the bipolar coagulator-cutter could result in tissue burn and electrical shock. (c) Infection: If the device is not properly sterilized, it may introduct microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that bipolar endoscopic coagulator-cutters and accessories be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and has sought other information and data describing the application of the bipolar endoscopic coagulator-cutter and accessories. Some of the literature suggests that this device is effective (Ref. 3), but long-term data are needed to demonstrate that this device can perform as well as alternate methods (Ref. 4).

The Commissioner believes that the device is purported or represented to be for a use (female sterilization) that is of substantial importance in preventing impairment of human health. The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient if an ectopic or contraindicated pregnancy occurs as a result of a device failure. The Commissioner concurs that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he also believes that insufficient information exists to establish a performance standard which will provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk and may be seen by interesed persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the First Meeting of the Endoscopic and Electrosurgical Subcommittee of the Ob-Gyn Device Classification Panel, October 1976.

2. Corson, S. L., "Bipolar Electrosurgery in Laparoscopy," Attachment A to Summary Minutes of the Second Meeting of the Endoscopic and Electrosurgical Subcommittee of the Ob–Gyn Device Classification Panel, January 1977.

3. Yuzpe, A. A., R. J. Anderson, N. P. Cohen, and J. L. West, "A Review of 1,035 Tubal Sterilizations by Posterior Colpotomy Under Local Anesthesia or by Laparoscopy," *The Journal of Reproductive Medicine*, 13:106–109, September 1974.

4. Wortman, J., "Tubal Sterilization—Review of Methods," *Population Reports*, Series C, No. 7, C73–C95, May 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4150 as follows:

§ 884.4150 Bipolar endoscopic coagulator-cutter and accessories.

(a) *Identification.* A bipolar endoscopic coagulator-cutter is a device used to perform female sterilization and other operative procedures under endoscopic observation. It destroys tissue with high temperatures by directing a high frequency electrical current through tissue between two electrical contacts of a probe. This generic type of device includes the following accessories: an electrical generator, probes, and electrical cables.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday thorugh Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1144]

[FR Doc. 79–9447 Filed 4–2–79; 8:45 am]
BILLING CODE 4110–03–M]

[21 CFR Part 884]

Classification of Unipolar Endoscopic Coagulator-Cutters and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying unipolar endoscopic coagulator-cutters and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–755.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elswhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of unipolar endoscopic coagulator-cutters and accessories:

1. Identification: A unipolar endoscopic coagular-cutter is a device designed to destroy tissue with high temperatures by directing a high frequency electrical current through the tissue between an energized probe and a gounding plate. It is used in female sterilization and other operative procedures under endoscopic observation. This generic type of device included the following accessories: An electrical generator, probes and electrical cables, and a patient grounding plate. This generic type of device does not include devices used to perform female sterilization under hsyteroscopic observation. The Panel previously considered this generic type of device under the names "culdoscopic coagulator and accessories," "hysteroscopic coagulator and acccessories" (which is for use in operative procedures other than sterilization), and "unipolar laparoscopic coagulator and accessories."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that unipolar endoscopic coagulator-cutters and accessories be classified into class II (performance standards) because the Panel believes that electrical safety standards are required to minimize the hazards of electrical shock, particularly those from the high frequency current used by the device. The Panel recommends that the device have proper current control, a grounding plate of standardized size, and an electrically insulated assembly. The Panel believes that device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel also recommends that the method of sterilizing the device be stated in the labeling, to prevent infection. The Panel notes that when this device is used with other devices, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, this device. Published data and Panel experience show widespread clinical use of this device. Of 146,976 tubal sterilizations by laparoscopy, the failure rate was 0.189 percent and the complication rate was 0.53 percent (Ref. 1). The data on coagulation with culdoscopy extends over many years with approximately equivalent results (Ref. 2). The Panel recommends discontinuing the use of the spark-gap generator because the peak voltage is higher than necessary even at low settings. The Panel recommends that for the unipolar coagulator-cutter, the open circuit peak voltage should not exceed 600 volts and that the power output through a low resistance of 200–500 ohms, nonreactive, should not exceed 100 watts. If the above recommendations are not followed, the nonconductive sleeve for the scope is dangerous and should not be used. In addition, the second trocar sleeve (through which an electrosurgical instrument may be introduced) should be nonconductive. The Panel also believes that data are not sufficient at this time to approve sterilization with the unipolar endoscopic coagulator-cutter as an accepted hysteroscopic technique. Clinical studies are being conducted to investigate this procedure (Refs. 3 and 4).

5. Risks to health: (a) Burns: Poor design or incorrect application of the device could result in tissue burns, particularly bowel burns, when the device heats the patient's tissue. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (c) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (d) Adverse tissue reaction: Material in the device could cause a local tissue or systemic reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that unipolar endoscopic coagulator-cutters and accessories not for use in hysteroscopic sterilization be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation and has obtained other data and information describing the application of unipolar endoscopic coagulator-cutters and accessories. The available literature indicates that this is a modality for which satisfactory performance standards can be developed (Refs. 5 and 6). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Phillips, J., D. Keith, L. Keith, J. Hulka, and B. Hulka, "Survey of Gynecologic Laparoscopy for 1974," *The Journal of Reproductive Medicine*, 15:45–50, August 1975.

2. Bank, A. H., "Culdoscopic Tubal Sterilization," *Fertility and Sterility*, 24:155–157, February 1973.

3. Bartsich, E. G. and T. F. Dillon, "Carbon Dioxide Hysteroscopy," *The American Journal of Obstetrics and Gynecology*, 124:746–750, April 1976.

4. Valle, R. F. and J. J. Sciarra, "Hysteroscopy: A Useful Diagnostic Adjunct in Gynecology," *The American Journal of Obstetrics and Gynecology*, 122:230–235, May 1975.

5. Clyman, M. J., "Operative Culdoscopy," *Obstetrics and Gynecology*, 32:840–845, December 1968.

6. Wortman, J., "Tubal Sterilization—Review of Methods," *Population Reports*, Series C, No. 7:C73–C95, May 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4160 as follows:

§ 884.4160 Unipolar endoscopic coagulator-cutter and accessories.

(a) *Identification.* A unipolar endoscopic coagulator-cutter is a device designed to destory tissue with high temperatures by directing a high frequency electrical current through the tissue between an energized probe and a grounding plate. It is used in female sterilization and in other operative procedures under endoscopic observation. This generic type of device includes the following accessories: An electrical generator, probes and electrical cables, and a patient grounding plate. This generic type of device does not include devices used to perform female sterilization under hysteroscopic observation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1145]

[FR Doc. 79–9448 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Expandable Cervical Dilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying expandable cervical dilators into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of expandable cervical dilators:

1. Identification: An expandable cervical dilator is an instrument with two handles and two opposing blades used manually to dilate (stretch open) the cervix.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that expandable cervical dilators be classified into class III (premarket approval) because the Panel believes that it is not possible to establish an adequate performance standard for this device. The design characteristics of this device are such that a standard cannot be established now which would assure a safe, evenly distributed cervical dilation. Safer methods of cervical dilation are available that do not have the high risk of cervical tears and laceration associated with the use of the expandable cervical dilator. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel members' experience with the

expandable cervical dilator has been that its leverage is very difficult to control in such a way that the cervix is dilated evenly. The Panel believes that more data concerning these types of dilators are necessary before standards can be written.

5. Risks to health: (a) Laceration of the cervix: Appropriate design and materials are necessary to prevent trauma to the cervix and possible subsequent infertility. (b) Adverse tissue reaction: Material in the device could cause a local tissue or systematic reaction when the device comes in contact with the patient. (c) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that expandable cervical dilators be classified into class III (premarket approval). The Commissioner believes that the device is purported or represented to be for a use (cervical dilation) that is of substantial importance in preventing impairment of human health. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because its safety and efficacy have not been proven, and safer alternate methods are now available. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4250 as follows:

§ 884.4250 Expandable cervical dilator.

(a) *Identification:* An expandable cervical dilator is an instrument with two handles and two opposing blades used manually to dilate (stretch open) the cervix.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1146]

[FR Doc. 79–0449 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Hygroscopic-Laminaria Cervical Dilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hygroscopic-laminaria cervical dilators into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–75555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of hygroscopic-laminaria cervical dilators:

1. Identification: A hygroscopic-laminaria cervical dilator is a device designed to dilate (stretch open) the cervix by cervical insertion of a conical and expansible material made from the root of a seaweed (laminaria digtata).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that hygroscopic-laminaria cervical dilators be classified into class II (performance standards) because the Panel believes that a standard can assure that the device, which is susceptible to contamination by spores, is sterile. The Panel recommends that the method of sterilization be stated in the labeling. The Panel believes that general controls alone will not provide sufficient control over this characteristic. The panel also recommends that the labeling state that the device is nonreusable. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on experience with, and personal knowledge of, the device. The Panel reviewed the literature on the device. In a typical study of 1,000 instances of laminaria use, there were no uterine perforations and only 4 cervical lacerations (Ref. 1). The device has occasionally migrated after insertion and broken up when removal was attempted (Ref. 2). After ethylene oxide gas sterilization, laminaria cervical dilators may be safely used. This device has been in use for a long time, and the Panel's experience indicates that sufficient data exist to develop a performance standard.

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. The risk of infection increases if the device migrates into the uterus. (b) Laceration of the cervix: If the device is not designed correctly, trauma to the cervix and possible subsequent infertility could occur.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that hygroscopic-laminaria cervical dilators be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide

reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Golditch, I. M. and M. H. Glasser, "The Use of Laminaria Tents for Cervical Dilation Prior to Vacuum Aspiration Abortion," *The American Journal of Obstetrics and Gynecology, 114:481–485, June 1974.*

2. Hanson, F. W., K. R. Niswander, and J. D. Trelfore, "Cervical Migration of Laminaria Tents," *The American Journal of Obstetrics and Gynecology,* 114:835–837, November 1972.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4260 as follows:

§ 884.4260 Hygroscopic-laminaria cervical dilator.

(a) *Identification.* A hygroscopic-laminaria cervical dilator is a device designed to dilate (stretch open) the cervix by cervical insertion of a conical and expansible material made from the root of a seaweed (laminaria digtata). The device is used to induce abortion.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–01147]

[FR Doc. 79–9450 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Vibratory Cervical Dilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vibratory cervical dilators into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of vibratory cervical dilators:

1. Identification: A vibratory cervical dilator is a device designed to enlarge the cervix by stretching it with a power-driven vibrating probe head. The device is used to gain access to the uterus or to induce abortion but is not to be used during labor.

2. Recommended classification: Class III (premarket approval). the Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that vibratory cervical dilators be classified into class III (premarket approval) because the Panel believes that it is not possible to establish an adequate performance standard for this device. The design characteristics of the device are such that a standard cannot be established now which would assure a safe, evenly distributed cervical dilation. Safer methods of cervical dilation are available that do not have the high risk of cervical tears and laceration associated with the use of vibratory dilators. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based is recommendation on experience with, and personal knowledge of, the device. The Panel reviewed the literature on the device and in a typical study of 50 patients, there were 3 failures to dilate and 3 patients with cervical tears (Ref. 1). The Panel believes that more data concerning these types of dilators are necessary before standards can be written.

5. Risks to health: (a) Laceration of the cervix: Appropriate design and materials are necessary to prevent trauma to the cervix and possible subsequent infertility. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient. (d) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commission agrees with the Panel recommendation and is proposing that vibratory cervical dilators be classified into class III (premarket approval). The Commissioner believes that the device is purported or represented to be for a use (cervical dilation) that is of substantial importance in preventing impairment of human health. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because its safety and effectiveness have not been proven, and safer, alternate methods are currently available. The Commissioner believes that insufficient information exists to determine that several controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Ng, A. Y. H., "Use of the Vibro Dilator in Outpatient Termination of Pregnancy," *Australia and New Zealand Journal of Obstetrics and Gynecology*, 13:228–230, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.270 as follows:

§ 8844.4270 Vibratory cervical dilator.

(a) *Identification.* A vibratory cervical dilator is a device designed to enlarge the cervix by stretching it with a power-driven vibrating probe head. The device is used to gain access to the uterus or to induce abortion but is not to be used during labor.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs

[Docket No. 78N–1148]

[FR Doc. 79–9451 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Fetal Vacuum Extractors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fetal vacuum extractors into class II (performance standards). The FDA is also publishing the recommendation of the Obsterical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of fetal vacuum extractors:

1. Identification: A fetal vacuum extractor is an obstetric device used to facilitate delivery. It applies traction to the fetal head (in the birth canal) by means of a suction cup attached to the scalp and is powered by an external vacuum source. This generic type of device may include the vacuum source and vacuum control.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that fetal vacuum extractors be classifed into class II (performance standards) because the Panel believes that design standards are necessary to prevent excessive vacuum and consequent fetal trauma. The Panel recommends a calibrated vacuum control to minimize this hazard. The Panel believes that material standards are necessary to assure rigid tubing that will not collapse under vacuum. The material of the cup must be flexible and must readily conform to the shape of the fetal head. The Panel believes that device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel believes that general controls alone will not provide sufficient controls over these characteristics. The Panel stated that this device should not be used in the case of a breech presentation. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on experience with, and personal knowledge of, the device and on a review of the literature on the device. Since the early 1950's, the vacuum extractor has been in wide use in many European countries with an associated decrease in pernatal mortality (Ref. 1). The Panel warns against applying the vacuum extractor for an excessive time and against developing the vacuum too quickly; either of these practices could cause fetal trauma. The Panel mentioned that use of this device presents less overall risk than forceps delivery and that most of the serious complications reported are associated with misuse of the vacuum extractor. The Panel noted that no brain damage or morbidity in infants extracted by vacuum has been reported, although the device may cause superficial scalp damage, for example, a cephalohematoma (blood cyst of the scalp).

5. Risks to health: (a) Adverse tissue reaction: Material in the device could result in a systemic or local tissue reaction when the device contacts the patient. (b) Trauma: A rigid vacuum cup, collapse of suction hose, or excessive vacuum in the device could result in a part of the device injuring the fetus.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that fetal vacuum extractors be classified into class II (performance standards.) The Commissioner has reviewed the Panel recommendation and has obtained additional data and information describing the application of vacuum extractors.

The Commissioner notes that careful choice of candidates for vacuum extraction and adherence to principles of application and traction technique are essential for reduction of incidence of fetal scalp trauma (Ref. 2). The Commissioner cautions that there is risk of fetal hemorrhage when use of the vacuum extractor follows fetal blood sampling (Ref 3). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by

interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Ott, W. J., "Vacuum Extraction," *Obstretical and Gyneological Survey,* 30:643–649, 1973.

2. Plauche, W. C., "Vacuum Extraction: Use in a Community Hospital Setting," *Obstetrics and Gynecology,* 52(3):289–293, September 1978.

3. Roberts, J. F. and M. Stone, "Fetal Hemorrhage: Complications of Vacuum Extractor after Fetal Blood Sampling," *American Journal of Obstetrics and Gynecology,* 132(1):109, September 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (seq. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4340 as follows:

§ 884.4340 Fetal vacuum extractor.

(a) *Identification.* A fetal vacuum extractor is an obstetric device used to facilitate delivery. It applies traction to the fetal head (in the birth canal) by means of a suction cup attached to the scalp and is powered by an external vacuum source. This generic type of device may include the vacuum source and vacuum control.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1149]

[FR Doc. 79–9452 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Obstetric Forceps

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying obstetric forceps into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of obstetric forceps:

1. Identification: An obstetric forceps is a device with two blades and handles. It is intended to grasp and apply traction to the fetal head in the birth passage and facilitate delivery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that obstetric forceps be classified into class II (performance standards) because the Panel believes that to prevent trauma, material standards are necessary to assure appropriate surface finish and strength. The Panel believes that general controls alone will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device, and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on experience with, and personal knowledge of, the device.

5. Risks to health: Trauma: Breakage, rough surface finish, or mechanical failure of the device could cause injury to the patient or the fetus.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that obstetric forceps be classified into class II (performance standards). The Commissioner notes that the use of forceps can cause many types of injury to both mother and baby (Ref. 1), in addition to the risks to health identified by the Panel. Many of these injuries result from errors in physicians' judgment, rather than characteristics of the device itself (Ref. 1).

The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Benson, R. C., *Current Obstetric and Gynecologic Diagnosis and Treatment,* 3d Ed., 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4400 as follows:

§ 884.4400 Obstetric forceps.

(a) *Identification.* An obstetric forceps is a device with two blades and handles. It is intended to grasp and apply traction to the fetal head in the maternal passage and facilitate delivery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be

submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs

[Docket No. 78N-1150]

[FR Doc. 79-9453 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Obstetric Fetal Destructive Instruments

AGENCY: Food and Drug Adminstration

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying obstetric fetal destructive instruments into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of obstetric fetal destructive instruments:

1. Identification: An obstetric fetal destructive instrument is a device designed to crush or pull the fetal body to facilitate the delivery of a dead or anomalous (abnormal) fetus. The Panel includes in this generic type of device those devices identified as "cleidoclast," "cranioclast," "craniotribe," and "destructive hook."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the obstetric fetal destructive instrument be classified into class II (performance standards) because the Panel believes that material standards are necessary to assure an adequate surface finish and appropriate tensile strength to prevent the hazards of trauma to the maternal vagina, cervix, or uterus. The Panel believes that general controls alone will not provide sufficient control over the characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. Obstetric fetal destructive instruments have been used for many years, but are not generally used in modern obstetrics. The Panel recommends that this device be used only in extensive circumstances where safer means of delivery are not possible.

5. Risks to health: (a) Laceration of the vagina, cervix, and uterus: If the materials or surface finish of this device are inadequate, injury or puncture of the maternal vagina, cervix, or uterus can result. (b) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that obstetric fetal destructive instruments be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4500 as follows:

§ 884.4500 Obstetric fetal destructive instrument.

(a) *Identification.* An obstetric fetal destructive instrument is a device designed to crush or pull the fetal body to facilitate the delivery of a dead or anomalous (abnormal) fetus. The Panel includes in this generic type of device those devices which were named cleidoclast, cranioclast, craniotribe, and destructive hook.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the office of Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs

[Docket No. 78N-1151]

[FR Doc. 79-9454 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Obstetric-Gynecologic General Manual Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying obstetric-gynecologic general manual instruments into class I (general controls). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls

applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1978. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of obstetric-gynecologic general manual instruments:

1. Identification: An obstetric-gynecologic general manual instrument is one of a group of devices used to perform simple obstetric and gynecologic manipulative functions. This generic type of device consists of the following:

Episiotomy scissors—a cutting instrument with two opposed shearing blades, used for surgical incision of the vulvar orifice for obstetrical purposes.

Fiberroptic metal vaginal speculum—a metal instrument, with fiberoptic light, used to expose the interior of the vagina.

Metal vaginal speculum—a metal instrument used to expose the interior of the vagina.

Umbilical scissors—a cutting instrument with two opposed shearing blades, used to cut the umbilical cord.

Uterine clamp—an instrument used to effect the compression of the uterus.

Uterine packer—an instrument used to introduce dressings into the uterus or vagina.

Vaginal applicator—an instrument used to insert medication into the vagina.

Vaginal retractor—an instrument used to maintain vaginal exposure by separating the edges of the vagina and holding back the tissue.

Gynecological fibroid hook—an instrument used to exert traction upon a fibroid.

Pelvimeter (external)—an instrument used to measure the external diameters of the pelvis.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that obstetric-gynecologic general manual instruments be classified into class I because their effectiveness can easily be determined by examination. General controls are sufficient to provide reasonable assurance of the safety and effectiveness of this generic type of device. Obstetric-gynecologic general manual instruments make no electrical contact with the patient and present no inherent hazards. The Panel originally made individual recommendations for episiotomy scissors, fiberoptic metal vaginal speculums, metal vaginal speculums, umbilical scissors, uterine clamps, uterine packers, vaginal applicators, vaginal retractors, gynecological fibroid hooks, and pelvimeters (external). Because it came to the same conclusion on each of these devices, the Panel recommended that those, and other substantially equivalent, devices be grouped in one category, for obstetric-gynecologic general manual instruments.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the devices. Obstetric-gynecologic general manual instruments have been used for many years. These devices are simple and present no risks to health. The effectiveness of their performance can be easily determined by examination. The Panel recommended that caution be used in making decisions about use of the vaginal applicator during pregnancy. If the vaginal applicator is reusable, an effective cleaning procedure should be specified, and the device should be appropriately packaged.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that obstetric-gynecologic general manual instruments be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4520 as follows:

§ 884.4520 Obstetric-gynecologic general manual instrument.

(a) *Identification.* An obstetric-gynecologic general manual instrument is one of a group of devices used to perform simple obstetric and gynecologic manipulative functions. This generic type of device consists of the following:

(1) An episiotomy scissors is a cutting instrument, with two opposed shearing blades, used for surgical incision of the vulvar orifice for obstetrical purposes.

(2) A fiberoptic metal vaginal speculum is a metal instrument, with fiberoptic light, used to expose the interior of the vagina.

(3) A metal vaginal speculum is a metal instrument used to expose the interior of the vagina.

(4) An umbilical scissors is a cutting instrument, with two opposed shearing blades, used to cut the umbilical cord.

(5) A uterine clamp is an instrument used to effect the compression of the uterus.

(6) A uterine packer is an instrument used to introduce dressing into the uterus or vagina.

(7) A vaginal applicator is an instrument used to insert medication into the vagina.

(8) A vaginal retractor is an instrument used to maintain vaginal exposure by separating the edges of the vagina and holding back the tissue.

(9) A gynecological fiberoid hook is an instrument used to exert traction upon a fibroid.

(10) A pelvimeter (external) is an instrument used to measure the external diameters of the pelvis.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 4, 1979, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1152]

[FR Doc. 79–9455 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Obstetric-Gynecologic Specialized Manual Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying obstetric-gynecologic specialized manual instruments into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of obstetric-gynecologic specialized manual instruments.

1. Identification: An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance. This type of device consists of the following:

Amniotome—an instrument used to rupture the fetal membranes.

Circumcision clamp—an instrument used to compress the foreskin of the penis during circumcision of a male infant.

Umbilical clamp—an instrument used to compress the unbilical cord.

Uterine curette—an instrument used to scrape and remove material from the uterus.

Fixed-size cervical dilator—any of a series of bougies of various sizes used to enlarge the cervix by stretching.

Uterine elevator—an instrument inserted into the uterus used to lift and manipulate the uterus.

Gynecological surgical forceps—an instrument with two blades and handles used to pull, grasp, or compress during gynecological examination.

Cervical cone knife—a cutting instrument used to excise and remove tissue from the cervix.

Gynecological cerclage needle—a sharp looplike instrument used to suture.

Hook-type contraceptive intrauterine device (IUD) remover—an instrument used to remove an IUD from the uterus.

Gynecological fibroid screw—an instrument used to hold onto a fibroid.

Uterine sound—an instrument used to determine the depth of the uterus.

Cytological cervical spatula—a blunt instrument used to scrape and remove cytological material from the surface of the cervix or vagina.

Gynecological biopsy forceps—an instrument with two blades and handles used for gynecological biopsy procedures.

Uterine tenaculum—a hooklike instrument used to seize and hold the cervix or fundus.

Internal pelvimeter—an instrument used to measure the diameters and capacity of the pelvis within the vagina.

Nonmetal vaginal speculum—a nonmetal instrument used to expose the interior of the vagina.

Fiberoptic nonmetal vaginal speculum—a nonmetal instrument, with fiberoptic light, used to expose the interior of the vagina.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performace standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that obstetric-gynecologic specialized manual instruments be classified into class II (performance standards) because a design standard will assure that the structural properties of these devices, e.g., shape, are adequate for their safe and effective use. A material standard is necessary to assure an adequate surface finish and appropriate tensile strength, which could be responsible for tissue trauma. The Panel believes that materials used in the device should be biocompatible to prevent an adverse tissue reaction. The Panel also recommends that the method of sterilization of this device be stated in the device labeling. The Panel believes that general controls alone will not provide sufficient control over the characteristics mentioned above. The Panel originally made individual recommendations for the following devices: amniotome, circumcision clamp, umbilical clamp, uterine curette, fixed-size cervical dilator, uterine elevator, gynecological biopsy forceps, gynecological surgical forceps, cervical cone knife, gynecological cerclage needle, hook-type intra uterine contraceptive device remover, gynecological fibroid screw, uterine sound, cytological cervical spatula, nonmetal vaginal speculum, fiberoptic nonmetal vaginal speculum, uterine tenaculum, and internal pelvimeter. Because the Panel came to the same conclusion on each of these devices, the Panel recommended that those and other substantially equivalent devices be grouped in one category for obstetric-gynecologic specialized manual instruments. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue damage: If the materials, surface finish, cleanliness, or form of this device are inadequate, damage to tissue can result. (b) Adverse tissue reaction: Material or substances in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient. (c) Infection: if the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that obstetric-gynecologic specialized manual instruments be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4530 as follows:

§ 884.4530 Obstetric-gynecologic specialized manual instrument.

(a) *Identification.* An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g.,

dilating, grasping, measuring, and scraping), where structual integrity is the chief criterion of device performance. This type of device consists of the following:

(1) An amniotome is an instrument used to rupture the fetal membranes.

(2) A circumcision clamp is an instrument used to compress the foreskin of the penis during circumcision of a male infant.

(3) An umbilical clamp is an instrument used to compress the umbilical cord.

(4) A uterine curette is an instrument used to scrape and remove material from the uterus.

(5) A fixed-size cervical dilator is any of a series of bougies of various sizes used to enlarge the cervix by stretching.

(6) A uterine elevator is an instrument inserted into the uterus used to lift and manipulate the uterus.

(7) A gynecological surgical forceps is an instrument with two blades and handles used to pull, grasp, or compress during gynecological examination.

(8) A cervical cone knife is a cutting instrument used to excise and remove tissue from the cervix.

(9) A gynecological cerclage needle is a sharp looplike instrument used to suture.

(10) A hook-type contraceptive intrauterine device (IUD) remover is an instrument used to remove an IUD from the uterus.

(11) A gynecological fibroid screw is an instrument used to hold onto a fibroid.

(12) A uterine sound is an instrument used to determine the depth of the uterus.

(13) A cytological cervical spatula is a blunt instrument used to scrape and remove cytological material from the surface of the cervix or vagina.

(14) A gynecological biopsy forceps is an instrument with two blades and handles used for gynecological biopsy procedures.

(15) A uterine tenaculum is a hooklike instrument used to seize and hold the cervix or fundus.

(16) An internal pelvimeter is an instrument used to measure the diameters and capacity of the pelvis within the vagina.

(17) A nonmetal vaginal speculum is a nonmetal instrument used to expose the interior of the vagina.

(18) A fiberoptic nonmetal vaginal speculum is a nonmetal instrument, with fiberoptic light, used to expose the interior of the vagina.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1153]

[FR Doc. 79–9456 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Gynecologic Surgical Lasers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gynecologic surgical lasers into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of gynecologic surgical lasers:

1. Identification: A gynecologic surgical laser is a continuous wave carbon dioxide laser designed to destroy tissue thermally or to remove tissue by radiant light energy. This device is used only in conjunction with a colposcope as part of a gynecological surgical system. A colposcope is a magnifying lens system used to examine the vagina and cervix. The Panel considered this generic type of device under the name "gynecological surgical laser-powered instrument and accessories."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that gynecologic surgical lasers be classified into class II (performance standards) because the radiant energy of the laser must be controlled to prevent unintended burns, to allow precise laser beam manipulation, and to protect the operator's eyes from stray laser beam reflection. The Panel also believes that electrical safety standards are necessary to prevent electrical shock. The Panel makes this recommendation on the condition that the manufacturer make no claim with regard to eradication of premalignant or malignant lesions. The Panel noted that when this device is used with other devices, e.g., the colposcope, the combination must be compatible. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel also reviewed the literature on the device and listed representative material. The carbon-dioxide laser has been in use for several years, and data presented to the Panel demonstrate that it is quite effective in destroying tissue (Refs. 1 and 2). The device must meet the laser safety performance standards of Part 1040 (21 CFR Part 1040). The current state of followup studies does not provide adequate data to demonstrate that laser-treated premalignant lesions do not recur.

5. Risks to health: (a) Burn: Poor design or incorrect application could result in tissue burns when the laser beam strikes tissue with

unintended intensity or without the necessary precision. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Unintended radiation: Malfunction of the shielding or structure of the control mechanism, allowing an escape of radiation greater than that needed for medical use, could result in severe tissue burns. The Panel notes further that users should use specially treated metal instruments to ensure safe heat dissipation. (d) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that gynecologic surgical lasers be classified into class II (performance standards). The Commissioner believes that many of the risks to health presented by the device are controlled by the performance standards for laser products in §§ 1040.10 and 1040.11 (21 CFR 1040.10 and 1040.11). These standards were promulgated under the Radiation Control for Health and Safety Act (42 U.S.C. 263b–n). There are, however, other risks presented by surgical lasers (e.g., electrical shock, and risks associated with use in combination with the colposcope) that are not controlled by the present performance standards. These other risks should be controlled in future supplemented standards promulgated under section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d). The Commissioner believes that performance standards are necessary for this device because general controls by themselves are insufficient to control the risks to health. The present and future performance standards for surgical lasers would provide reasonable assurance of their safety and effectiveness. The Commissioner also believes that there is sufficient information to establish standards to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Morrow, C. P. and D. E. Townsend, "Management of Adenosis and Clear-Cell Adenocarcinoma of Vagina and Cervix," **The Journal of Reproductive Medicine**, 15:25–28, July 1975.

2. Stafl, A., E. J. Wilkinson, and R. F. Mattingly, "Laser Treatment of Cervical and Vaginal Neoplasia," **American Journal of Obstetrics and Gynecology**, 128:128–136, May 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4550 as follows:

§ 884.4550 Gynecologic surgical laser.

(a) *Identification.* A gynecologic surgical laser is a continuous wave carbon dioxide laser designed to destroy tissue thermally or to remove tissue by radiant light energy. The device is used only in conjunction with a colposcope as part of a gynecological surgical system. A colposcope is a magnifying lens system used to examine the vagina and cervix.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1154]

[FR Doc. 79–9457 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Obstetric Tables and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying obstetric tables and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of the obstetric table and accessories:

1. Identification: An obstetric table is a device with adjustable sections used to support a patient in the various positions required during obstetric and gynecologic procedures. This generic type of device may include the following accessories: patient equipment, support attachments, and cabinets for warming instruments and disposing of wastes. The Panel includes in this generic type of device those devices identified as "AC-powered obstetric table and accessories," "manual obstetric table and accessories," and "lithotomy drape clip."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the obstetric table and accessories be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure effective operation of the device with minimal danger. The mechanical design of these devices must allow manual override of powered moves and safe movement of parts without the risk of catching fingers in hinges and other moving parts. The Panel recommends electrical safety standards to minimize the hazards of electrical shock. The Panel believes that material standards are necessary to assure the device is strong enough to support the patient during typical

labor stresses. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the device.

5. Risks to health: (a) Trauma: Without appropriate mechanical safety and design considerations e.g., mechanical strength, guarded hinges, fail-safes, and overrides, the patient and operator face the risk of physical injury. (b) Electrical Shock: Malfunction of the device could result in electrical shock to the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that obstetric tables and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart E by adding new § 884.4900 as follows:

§ 884.4900 Obstetric table and accessories.

(a) *Identification.* An obstetric table is a device with adjustable sections designed to support a patient in the various positions required during obstetric and gynecologic procedures. This generic type of device may include the following accessories: patient equipment, support attachments, and cabinets for warming instruments and disposing of wastes.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated March 15, 1979.

William F Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78–1155]

[FR Doc. 79–9458 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Metreurynter-Balloon Abortion System

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying metreurynter-balloon abortion systems into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application as a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of metreurynter-balloon abortion systems:

1. Identification: A metreurynter-balloon abortion system is a device used to induce abortion. The device dilates the cervix by inflating a balloonlike dilator placed in the cervical canal. This generic type of device may include pressure sources and pressure controllers.

2. Recommended classification. Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the metreurynter-balloon abortion system be classified into class III (premarket approval) because the Panel believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device in the United States. Therefore, the device must be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' familiarity with the device and a review of the literature on this device. Although journal articles discussing the use of this device in Japan indicate that it may be safe and effective (Refs. 1 and 2), the Panel believes that these data are inconclusive and that more studies need to be performed to establish the performance characteristics of the device. A standard textbook mentions that the device is rarely used because of potential trauma or infection, unpredictability, and the risk of a live-born fetus (Ref. 3).

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Trauma, laceration, hemorrhage, and perforation: Poor design of the device could cause uneven dilation of the cervix causing injury to the patient. (c) Adverse tissue reaction: Material or substances in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient's cervix. (d) Unnecessary medical procedures: Loss of the device could result in an otherwise unnecessary medical procedure to recover the device from the uterus.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that metreurynter-balloon abortion system devices be classified into class

III (premarket approval). The Commissioner has reviewed the Panel's recommendation and has obtained additional data and information describing the application of the metreurynter-balloon abortion system. An important summary monograph (Ref. 4) lists three major disadvantages of the device, and of the modified version of the device being investigated in the United States: (1) Increased risk of infection, (2) prolonged confinement, and (3) high incidence of live births. The review concludes "that knowledge is still deficient regarding both the natural process and induced procedures" of cervical dilatation.

The Commissioner believes that the device is purported or represented to be for a use (pregnancy termination) that is of substantial importance in preventing impairment of human health. The Commissioner also believes that the device presents a potential unreasonable risk of illness or injury because it may not be effective and may therefore cause serious harm. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Manable, Y. and A. Nakajima, "Laminaria Metreurynter Method of Midterm Abortion in Japan," *Obstetrics and Gynecology*, 40:612–615, 1972.

2. Manable, Y. et al., "Uterine Contractility and Placental Histology in Abortion by Laminaria and Metreurynter," *Obstetrics and Gynecology*, 41:753–759, 1973.

3. Benson, R. C., "Current Obstetric and Gynecologic Diagnosis and Treatment," Lange Medical Publications, Los Altos, Calif., 1976, pp. 840–841.

4. Population Reports, "Pregnancy Termination," Series F, Nos. 5 and 6, The George Washington University Medical Center, Washington, DC, 1976–1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 by adding new Subpart F and § 844.5050 to read as follows:

Subpart F—Obstetrical and Gynecological Therapeutic Devices

§ 884.5050 Metreurynter-balloon abortion system.

(a) *Identification.* A metreurynter-balloon abortion system is a device used to induce abortion. The device dilates the cervix by inflating a ballonlike dilator placed in the cervical canal. This generic type of device may include pressure sources and pressure controllers.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1156]

[FR Doc. 79–9459 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Vacuum Abortion Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vacuum abortion systems into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Admendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of vacuum abortion systems:

1. Identification: A vacuum abortion system is a device designed to aspirate transcervically the products of conception or menstruation from the uterus by using a cannula connected to a suction source. The device is used for pregnancy termination or menstrual regulation. This type of device may include the aspiration cannula, the vacuum source, and the vacuum controller. The Panel includes in this generic type of device those devices identified as "uterine suction cannula," "vacuum abortion unit controller," "vacuum abortion unit source," and "vacuum abortion unit system."

2. Recommended classification: Class II (performance standard). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that vacuum abortion systems be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure safe and effective uterine suction. These design standards would (1) limit the suction cannula diameter to prevent unnecessary cervical dilation, (2) assure appropriate calibration so that adequate suction pressure is within safety limits when applied, (3) incorporate a fail-safe mechanism to prevent excessive uterine pressure or vacuum, and (4) place the suction control on the handgrip to permit ease of handling to prevent uterine trauma. Because the vacuum abortion system is electrically powered, the Panel recommends that electrical safety standards be required to minimize the hazards of electrical shock. The Panel believes that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel also believes that a material standard is necessary to assure appropriate rigidity of the suction cannula so

that the cannula is flexible enough to prevent uterine trauma yet rigid enough not to collapse under vacuum. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on extensive experience with this abortion system and their review of the literature on the device. Many abortions using a vacuum abortion system have been performed in the United States, especially since the Supreme Court's decision in *Roe* v. *Wade,* 410 U.S. 113(1973), which invalidated many State restrictions on abortions. Reference articles report the need for a flexible cannula with a small diameter to reduce the risk of perforation (Refs. 1 and 2). Complications blamed on malfunction of the vacuum system have been documented; these show the necessity of failsafe mechanisms (Refs. 3 and 4).

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Laceration, perforation, or trauma: The patient could be injured by unnecessary cervical dilation, excessive vacuum, or material abrasions. (d) Adverse tissue reaction: Material used in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that vacuum abortion systems be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner is aware of the considerable body of data on abortion complications. These complications are basically determined by the duration of pregnancy and can be minimized by the use of proper abortion systems (Ref. 5).

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 5 p.m., Monday through Friday.

1. Young, P. E., "Abortion and Menstrual Extraction for the Ambulatory Patient," *Clinical Obstetrics and Gynecology,* 17:277–290, 1974.

2. Edelman, D. A., W. E. Brenner, and G. S. Berger, "The Effectiveness and Complications of Abortion by Dilatation and Vacuum Aspiration Versus Dilatation and Rigid Metal Curettage," *American Journal of Obstertics and Gynecology,* 119:473–480, 1974.

3. Kerslake, D. and D. Casey, "Abortion Induced by Means of the Uterine Aspirator," *Obstetrics and Gynecology,* 30:35–45, 1967.

4. Munsick, R., "Air Embolism and Maternal Death from Therapeutic Abortion," *Obstetrics and Gynecology,* 39:688–689, 1972.

5. Population Report, "Pregnancy Termination," Series F:Nos. 1 to 6, The George Washington University Medical Center, Washington, DC, 1973–1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5070 as follows:

§ 884.5070 Vacuum abortion system.

(a) *Identification.* A vacuum abortion system is a device designed to aspirate transcervically the products of conception or menstruation from the uterus by using a cannula connected to a suction source. This device is used for pregnancy termination or menstrual regulation. This type of device may include aspiration cannula, vacuum source, and vacuum controller.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78–1157]

[FR Doc. 79–9460 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Obstetric Anesthesia Sets

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying obstetric anesthesia sets into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of obstetric anesthesia sets:

1. Identification: An obstetric anesthesia set is an assembly of antiseptic solution, needles, needle guides, syringes, and other accessories, intended for use with an anesthetic drug. This device is used to administer regional blocks (e.g., paracervical, uterosacral, and pudendal), that may be used during labor, delivery, or both. The Panel includes in this generic type of device those devices identified as "paracervical

anesthesia set" and "pudendal anesthesia set."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that obstetric anesthesia sets be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure the appropriate length and gauge of the needles and needle guides to prevent hemorrhage and misapplication. The Panel believes that device materials contacting the body should meet a biocompatibility standard to prevent adverse tissue reaction. The Panel believes that material standards are necessary to assure an adequate surface finish and appropriate tensile strength to prevent trauma to tissue, damage to the cervix, and hemorrhage. The Panel recommends that the method of sterilization be stated in the device labeling. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on extensive experience with these obstetric anesthesia sets. The Panel members also reviewed the literature on the device which indicates appropriate specifications, indications, and other aspects of obstetric anesthesia (Ref. 1).

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

(b) Trauma, hemorrhage, and perforation: Inappropriate length or gauge of the needles and guides or breakage of the device could result in patient or fetus trauma, hemorrhage, and perforation.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that obstetric anesthesia sets be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation and has obtained other data and information describing the application of obstetric anesthesia sets. The practicality and safety of regional anesthesia, such as lumbar and caudal epidural blocks, subarachnoid blocks, lumbar sympathetic blocks, spinal anesthesia, paracervical blocks, and pudendal blocks, depends more upon the knowledge and skill of the physician and on the characteristics of the anesthesia used than upon the characteristics of obstetric anesthesia sets (Ref. 2). Spinal, caudal, and other anesthesia blocks are procedures requiring scrupulous preparation and aseptic techniques. The Commissioner believes that a performance standard is necessary for obstetric anesthesia sets because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Moore, Daniel C., "Regional Block," 4th Ed., Charles C. Thomas Publisher, Springfield, Ill., 1965.

2. McDonald, John S., "Obstetric Analgesia and Anesthesia," *in* "Current Obstetric and Gynecologic Diagnosis and Treatment," 2d Ed., Edited by Benson, R. C., Lange Medical Publications, Los Altos, CA, pp. 595–618. 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 844.5100 as follows:

§ 884.5100 Obstetric anesthesia set.

(a) *Identification.* An obstetric anesthesia set is an assembly of antiseptic solution, needles, needle guides, syringes, and other accessories, intended for use with an anesthetic drug. This device is used to administer regional blocks (e.g., paracervical, uterosacral, and pudendal) that may be used during labor, delivery, or both.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1158]

[FR Doc. 79–9461 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Nonpowered Breast Pumps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonpowered breast pumps into class I (general controls). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nonpowered breast pumps.

1. Identification: A nonpowered breast pump is a manual suction device used for postpartum extraction of milk from the breast.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that nonpowered breast pumps be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device. This simple device presents no risk to health and the user can easily determine, by examination, whether the device is effective. There have been no reports that the material in the device has caused an adverse tissue reaction.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, the manual breast pump. The device has been in use for many years.

5. Risks to health: Adverse tissue reaction: Material in the device could cause a local adverse tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that nonpowered breast pumps be classified into class I (general controls) with no exemptions because the Commissioner believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5150 as follows:

§ 884.5150 Nonpowered breast pump.

(a) *Identification.* A nonpowered breast pump is a manual suction device used for postpartum extraction of milk from the breast.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 4, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs

[Docket No. 78N–1159]

[FR Doc. 79–9462 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21CFR Part 884]

Classification of Powered Breast Pumps

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered breast pumps into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of powered breast pumps:

1. Identification: A powered breast pump is an electrically powered suction device used for postpartum extraction of milk from the breast.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that powered breast pumps be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure a standardized pressure control to prevent excessive suction pressure that might cause trauma to the nipple and breast. The Panel recommends that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel also recommends that electrical safety standards be required to minimize the hazards of electrical shock. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel recommends that the device labeling state: "excessive and prolonged use may cause injury to nipples". The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, powered breast pumps.

5. Risks to health: (a) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (b) Trauma: Failure to control excessive pressure of the device could result in injury to the patient's breasts and nipples. (c) Adverse tissue reaction: Materials in the device could result in a systemic or local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that powered breast pumps be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5160 as follows:

§ 884.5160 Powered breast pump.

(a) *Identification.* A powered breast pump is an electrically powered suction device used for postpartum extraction of milk from the breast.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1160]

[FR Doc. 79–9463 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Cervical Caps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cervical caps into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, make the following recommendation with respect to the classification of cervical caps:

1. Identification: A cervical cap is a flexible cuplike receptacle that fits over the cervix to collect menstrual flow or to aid artificial insemination. This generic type of device is not to be used as a contraceptive.

2. Recommended classification: Class II (performance standards). the Panel recommends that establishing a performance standard for this device be a low prioritty.

3. Summary of reasons for recommendation. The Panel recommends that cervical caps be classified into class II (performance standards) because the Panel believes that material standards are necessary to assure appropriate flexibility and rigidity of the materials used in the cervical cap to prevent trauma and laceration of the cervix. The Panel also states that this material should be biocompatible with the vaginal tissues to prevent adverse tissue reaction. The Panel notes that the cervical cap is not indicated as a contraceptive agent because its effectiveness for this use has not been proven in the United States. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, this device and the absence of adverse reports about cervical caps.

5. Risks to health: (a) Trauma: Rough edges of the device could result in injury to the patient's vagina or cervix. (b) Adverse tissue reaction: Material in the device could cause a local tissue or systemic reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the panel recommendation and is proposing that cervical caps be classified into class II (performance standards). The Commissioner also agrees with the Panel that there is a lack of effectiveness data on use of the cervical cap as a contraceptive agent in the United States (Ref. 1). The Commissioner believes that a performance standard is necessary for this device because general contols by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Population Reports, Series H, No. 4; "Barrier Methods," The George Washington Medical Center, Washington, DC, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5250 as follows:

§ 884.5250 Cervical cap.

(a) *Identification.* A cervical cap is a flexible cuplike receptacle that fits over the cervix to collect menstrual flow or to aid artificial insemination. This generic type of device is not be used as a contraceptive.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1161]

[FR Doc. 79–9464 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Abdominal Decompression Chambers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying abdominal decompression chambers into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of abdominal decompression chambers:

1. Identification: An abdominal decompression chamber is a hoodlike device used to reduce pressure on the pregnant patient's abdomen for the relief of abdominal pain during pregnancy or labor.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that abdominal decompression chambers be classified into class III (premarket approval) because satisfactory performance has never been demonstrated. This device is used primarily in foreign countries. The modality and the design of the device are not well understood. Therefore, the device must be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, this device. The Panel considers this device to be ineffective. Additionally, the Panel found no literature available to supply adequate clinical data supporting any claim of effectiveness. The consensus of the Panel was that any data which might be developed would support an action to ban the device because its risks outweigh its benefits.

5. Risks to health: (a) Difficult patient management: The device is cumbersome and covers the abdominal area of the patient, thus blocking the physician from examining the patient. (b) Supine hypotension: Because the patient is required to lie on her back, the possibility of induced low blood pressure and consequent complications exists.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that abdominal decompression chambers be classified into class III (premarket approval). Even though this device is in use, valid scientific data are lacking to support its safe and effective use.

The Commissioner believes that the device is purported or represented to be for a use (relief of pain) that is of substantial importance in preventing impairment of human health. The Commissioner believes that the device presents a potential unreasonable risk of illness or injury because its effectiveness is not proven and harm, such as cardiac complications, may result. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5225 as follows:

§ 884.5225 Abdominal decompression chamber.

(a) *Identification.* An abdominal decompression chamber is a hoodlike device used to reduce pressure on the pregnant patient's abdomen for the relief of abdominal pain during pregnancy or labor.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1162]

[FR Doc. 79–9465 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Condoms

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying condoms into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel and the General Hospital and Personal Use Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305).

Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of condoms:

1. Identification: A condom is a sheath which completely covers the penis with a closely fitting membrane. The condom is used for contraception and for prophylactic purpose (preventing transmission of veneral disease). The device may also be used to collect seminal fluid to aid in the diagnosis of infertility. The Panel considered this generic type of device under the name contraceptive condom ("rubber"). The General Hospital and Personal Use Device Classification Panel considered this device with respect to its prophylactic use.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The General Hospital and Personal Use Device Classification Panel and the Obstetrical and Gynecological Device Classification Panel recommend that condoms be classified into class II (performance standards) because materials in the device that come in contact with the penis or vagina should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panels believe material standards are necessary to assure the membrane integrity and elasticity of the condom to prevent unwanted pregnancy. The Panels believe that general controls alone will not provide sufficient control over these characteristics. The Panels also recommend that proper instructions concerning use, proper size, and shelf life (expiration date) of the device be stated in the device labeling. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the extensive experience with, and widespread use of, condoms for many years. The use, safety, and effectiveness of the device is well documented. (Ref. 1). In addition, there are existing manufacturers' association standards for this device.

5. Risks to health: (a) Venereal disease: If the device leaks or breaks, it may permit the passage of microorganisms that could cause infection. (b) Adverse tissue reaction: Material or substances in the device could cause a local tissue or systemic reaction when the device comes in contact with the patient or his partner. (c) Unwanted pregnancy: If the device leaks or breaks, it may permit the passage of sperm that could result in pregnancy.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that condoms be classified into class II (performance standards). The Commissioner believes that performance standards are necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Population Reports, Series H, Nos. 1 and 2, "Barrier Methods," The George Washington University Medical Center, Washington, DC, 1973–1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5300 as follows:

§ 884.5300 Condom.

(a) *Identification.* A condom is a sheath which completely covers the penis with a closely fitting membrane. The condom is used for contraception and for prophylactic purposes (preventing transmission of venereal disease). The device may also be used to collect seminal fluid to aid in the diagnosis of infertility.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1978 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockille, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1163]
[FR Doc. 79–9466 Filed 4–2–79; 8:45 am]
BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Contraceptive Diaphragms and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying contraceptive diaphragms and accessories into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classsification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of contraceptive diaphragms and accessories:

1. Identification: A contraceptive diaphragm is a closely fitting membrane placed between the posterior aspect of the pubic bone and the posterior vaginal fornix. The device covers the cervix completely and is used to prevent pregnancy. This generic type of device may include an introducer and other accessories. The Panel includes in this generic type of device those devices identified as "contraceptive diaphragm" and "contraceptive diaphragm introducer."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the contraceptive diaphragm and accessories be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure the correct shape. A material standard is also necessary to assure the rigidity and flexibility necessary to maintain that shape and to allow a close cervical fit. The Panel recommends that device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also recommends that device labeling state "to be used with spermicidal jelly or cream; refitting needed with weight loss or gain of 10 pounds or subsequent pregnancy," and the shelf life (expriation date) and date of manufacture. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, these contraceptive diaphragms. These devices have been in use for a long time. Their use is described in most textbooks (Ref. 1).

5. Risks to health: (a) Trauma, hemorrhage, and perforation: The form, finish, or structure of the device could result in injury to the patient. (b) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient. (c) Unwanted pregnancy: Failure of the device could result in pregnancy if the device breaks or leaks.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that contraceptive diaphragms and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also includes a review article on the diaphragm and other intravaginal barrier contraceptives, describing their methods of use and effectiveness (Ref. 2).

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Greenhill, J. C., "Office Gynecology," 9th Ed., Year Book Medical Publishers, Inc., 1971.

2. Population Reports, "Barrier Methods," Series H, No. 4, The George Washington University Medical Center, Washington, DC, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5350 as follows:

§ 884.5350 Contraceptive diaphragm and accessories.

(a) *Identification.* A contraceptive diaphragm is a closely fitting membrane placed between the posterior aspect of the public bone and the posterior vaginal fornix. The device covers the cervix completely and is used to prevent pregnancy. This generic type of device may include an introducer and other accessories.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commisioner for Regulatory Affairs.

[Docket No. 78N–1164]

[FR Doc. 79–9467 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Contraceptive Intrauterine Devices (IUD) and Introducers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying contraceptive intrauterine devices (IUD) and introducers into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological

Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of contraceptive intrauterine devices (IUD) and introducers:

1. Identification: A contraceptive intrauterine device (IUD) and introducer is a device that is placed high in the uterine fundus with a string extending from the uterus into the vagina and is used to prevent pregnancy. This generic type of device does not include products that function by drug activity, which are subject to the new drug provisions of the Federal Food, Drug, and Cosmetic Act.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that contraceptive intrauterine devices and their introducers be classified into class III (premarket approval) because the device is an implant. The device is inserted into a naturally formed cavity of the body and is intended to remain in the body for an indefinite period of time. The Panel believes that the device is a relatively safe and reliable means of contraception; however, accumulated evidence shows the need to evaluate the potential hazards of IUD's. Because the safety and effectiveness of the device depend on its design, the Panel members conclude that it is not possible to establish an adequate performance standard for this generic type of device. Therefore the device must be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on familiarity with the device and a review of the literature. The Panel and the Obstetrical and Gynecological Advisory Committee of the Bureau of Drugs prepared "The Report of Safety and Efficacy of the Dalkon Shield and Other IUD's" (Ref. 1). The Panel members reviewed the literature on the device and the FDA contract report, "Review and Analysis of the Scientific and Clinical Data on the Safety, Efficacy, Adverse Reactions, Biologic Action, Utilization, and Design of Intrauterine Devices" (Ref. 2). The Panel also reviewed and endorsed FDA's regulation on "Intrauterine Contraceptive Devices; Professional and Patient Labeling," published in the Federal Register of May 10, 1977 (42 FR 23772). The Panel members recommend that FDA amend the IUD labeling requirements to warn patients of the potential hazard of future infertility resulting from pelvic inflammatory disease.

5. Risks to health: (a) Pelvic inflammatory disease: Women who wear an IUD have a greater chance of developing pelvic inflammatory disease (PID) than nonusers. PID is a group of several pelvic infections that may infect the uterus, the faliopian tubes, and the ovaries. Symptoms of pelvic infection can include pelvic or abdominal pain, increasing pain with intercourse and menstruation, irregular bleeding (spotting, flooding, or passing clots), abnormal vaginal discharge, and occasional chills and fever. Furthermore, pelvic infection can seriously interfere with or prevent a woman's ability to become pregnant, especially if the tubes are affected by PID and become sufficiently scarred. (b) Perforation: Partial or total perforation of the uterine wall or cervix may occur with the use of IUD's. Foreign body reactions, peritonitis, adhesions, and intestinal obstructions may result if an IUD is left in the peritoneal cavity. Removal of an IUD which has perforated the uterus or cervix may require abdominal surgery including hysterectomy. (c) Ectopic (extrauterine) pregnancy: An IUD will not prevent a life-threatening ectopic pregnancy. (d) Abnormal menstrual pattern: An IUD user may develop an abnormal menstrual pattern, which may include delayed menstruation, intermittent spotting, prolonged or heavy menstrual flow, or unusual cramps. (e) Spontaneous abortion or miscarriage: When conception occurs, the incidence of spontaneous abortion is increased for IUD users. Spontaneous abortion is often accompained by serious hemorrhaging and may require hospitalization and transfusion. (f) Septic abortion: Reports have shown an increased incidence of septic abortion in patients becoming pregnant with an IUD in place. This condition is associated in some instances with septicemia, septic shock, and death. (g) Septicemia (blood poisoning): Infection associated with PID or septic abortion may result in septicemia. (h) Cervical infection: A woman who wears an IUD may develop a cervical infection. (i) Vaginal infection: A woman who wears an IUD may develop a vaginal infection. (j) Cysts of the ovaries and tubes: A woman who wears an IUD may develop a cyst on her ovaries and/or fallopian tubes. (k) Anemia: A woman who wears an IUD may develop anemia due to excessive loss of blood. (l) Complete or partial expulsion: The IUD may be expelled, either partially or totally, resulting in loss of contraception. (m) Embedment or difficult removal: If the IUD is difficult to remove, either because of partial penetration or lodging of the IUD in the endometrium or because of other reasons, surgery may be required to remove it. (n) Fragmentation: The IUD may fragment and initiate inflammatory responses. (o) Backache: An IUD user may develop backaches. (p) Unwanted pregnancy: Failure of the IUD could result in an unwanted pregnancy.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that contraceptive intrauterine devices (IUD) and introducers be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and recent literature describing the safety and effectiveness of IUD's (Refs. 3 and 4). The Commissioner believes that the device is purported or represented to be for a use (prevention of pregnancy) that is of substantial importance in preventing impairment of human health. He believes that the device also presents a potential unreasonable risk of illness or injury to the patient if there are not adequate data to assure the safe and effective use of this device. Furthermore, the device is an implant which the Federal Food, Drug, and Cosmetic Act requires to be classified into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of a device's safety and effectiveness. In this case, the Commissioner believes that premarket approval is necessary for the device because general controls and performance standards are insufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

The Commissioner agrees with the Panel that the IUD labeling requirements should be amended to warn patients of the potential hazard of future infertility resulting from pelvic inflammatory disease. The Commissioner intends to implement the Panel's recommendation in a future proposal in the Federal Register. The proposal will also improve the agency's ability to assure that new information on IUD's is made available to the public promptly. Additional references relating to intrauterine devices are on file with the Hearing Clerk under Docket No. 75N–0122, "Intrauterine Contraceptive Devices; Professional and Patient Labeling," which was published in the Federal Register of May 10, 1977 (42 FR 23772).

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Report of Safety and Efficacy of the Dalkon Shield and Other IUD's"; ad hoc Obstetrical and Gynecological Advisory Committee, Bureau of Drugs, Food and Drug Administration, October 29–30, 1974.

2. "Review and Analysis of the Scientific and Clinical Data on the Safety, Efficacy, Adverse Reactions, Biological Action, Utilization, and Design of Intrauterine Devices," Battelle Memorial Institute, Human Affairs Research Centers, August 11, 1975.

3. "Intrauterine Devices: An Invitational Symposium," A. Scommegna, Guest Editor, *The Journal of Reproductive Medicine*, 20:119–182, 1978.

4. Vessey, M. P., B. Johnson, R. Doll, and R. Peto, "Outcome of Pregnancy in Women

Using an Intrauterine Device," *The Lancet*, 1:495–498, March 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5360 as follows:

§ 884.5360 Contraceptive intrauterine device (IUD) and introducer.

(a) *Identification.* A contraceptive intrauterine device (IUD) and introducer is a device that is placed high in the uterine fundus with a string extending from the uterus into the vagina and is used to prevent pregnancy. This generic type of device does not include products that function by drug action, which are subject to the new drug provisions of the Federal Food, Drug, and Cosmetic Act.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1165]

[FR Doc. 79–9468 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Contraceptive Tubal Occlusion Devices (TOD) and Introducers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying contraceptive tubal occlusion devices (TOD) and introducers into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of contraceptive tubal occlusion devices (TOD) and introducers:

1. Identification: A contraceptive tubal occlusion device (TOD) and introducer is a device designed to close the fallopian tubes with a mechanical structure, e.g., a band or clip on the outside of the fallopian tubes or a plug or valve on the inside, that is used to prevent pregnancy. The Panel includes in this generic type of device those devices identified as "tubal occlusion band," "tubal occlusion clip," "tubal occlusion insert," and "tubal occlusion valve."

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that tubal occlusion devices and introducers be classified into class III (premarket approval) because the TOD is an implant. It is inserted in, or attached to, the fallopian tubes and is intended to remain in the body for an indefinite period of time. The Panel believes that there are insufficient data to establish an adequate performance standard for the design of a TOD and the long-term safety and effectiveness of the device. Failure of the device to close completely the fallopian tube could result in unwanted pregnancy or life-threatening ectopic (extrauterine) pregnancy. Furthermore, because the safety and effectiveness of the TOD depends on the design, the Panel concludes that it is not possible to establish an adequate performance standard for this generic type of device. Therefore, the device and its introducer should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness. The Panel stresses the need to study the tubal occlusion device and its introducer as an integral system to determine its safety and effectiveness. The Panel also recommends that the labeling state that the device is contraindicated in a patient with pelvic inflammatory disease or significant adnexal pathology (disease of uterine tubes or ovaries).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on information presented by experts to the Panel's Conception Control Devices Subcommittee (Ref. 1) and the Panel's review of the literature (Refs. 2, 3, and 4). One monograph concludes that large, long-term, randomized comparative studies are required to determine rates of failure and subsequent gynecological problems (Ref. 3). Although results of one study comparing the tubal ring procedure and electrocoagulation indicate that sterilization by tubal ring is safe and easy to perform, long-term comparative studies are needed "to evaluate the failure rates, changes in menstrual patterns, and the incidence of future gynecologic abnormalities" (Ref. 5). The Panel concluded that long-term safety and effectiveness have not been determined for any devices of this generic type.

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Trauma or perforation: Breakage of the device could cause a part of the device to injure or puncture the patient's tissues and organs. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes into contact with the patient. (d) Bowel obstruction: Improper design of the device could result in bowel obstruction if the device migrates from the fallopian tubes. (e) Unwanted pregnancy or ectopic (extrauterine) pregnancy: Unwanted pregnancy or life-threatening ectopic pregnancy may occur if the device fails to close the tubes permanently.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that tubal occlusion devices (TOD) and introducers be classified into class III (premarket approval). The Commissioner believes that the device is purported or represented to be for a use (female sterilization) that is of substantial importance in preventing

impairment of human health. The Commissioner reviewed a recent survey of available TOD equipment and procedures that indicates that bleeding associated with the use of tubal occlusion rings sometimes requires electrocoagulation, or even laparotomy, to achieve hemostasis (Ref. 6). The device is intended to be implanted into the human body. Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) requires the Commissioner to classify an implant into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

1. Summary Minutes of the Second Meeting of the Conception Control Subcommittee of the Obstetric and Gynecologic Device Classification Panel, June 1976.

2. Hulka, J. F., "Studies in Simpler Tubocclusion Methods," *American Journal of Obstetrics and Gynecology*, 122:337–348, 1975.

3. Brenner, W. E. and D. A. Edelman, "Early Complications of Sterilization in Women Who Have Not Recently Been Pregnant," *Surgical Gynecology and Obstetrics*, 140:69, 1975.

4. Brenner, W. E. et al., "Laparoscopic Sterilization with Electrocautery, Spring-Loaded Clips, and Silastic Bands—Technical Problems and Early Complications," unpublished paper.

5. Kwak, H. M., C. H. Song, A. Saba, "Laparoscopic Sterilization by Tubal Ring and Electrocoagulation," presented at the Second International Congress of Gynecologic Endoscopy of the International Fertility Research Program, Las Vegas, NV, 1975.

6. Population Reports, "M/F Sterilization Equipment," Special Topic Monographs (1), The George Washington University Medical Center, Washington, DC, Sept. 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540—546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5380 as follows:

§ 884.5380 Contraceptive tubal occlusion device (TOD) and introducer.

(a) *Identification.* A contraceptive tubal occlusion device (TOD) and introducer is a device designed to close the fallopian tubes with a mechanical structure, e.g., a band or clip on the outside of the fallopian tubes or a plug or valve on the inside, that is used to prevent pregnancy.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated March 15, 1979.

William F Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1166]

[FR Doc. 79–9469 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Perineal Heaters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying perineal heaters into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of perineal heaters:

1. Identification: A perineal heater is a device designed to apply heat directly by contact, or indirectly from a radiant source, to the surface of the perineum (the area between the vulva and the anus) and is used to soothe or to help heal the perineum after an episiotomy (incision of the vulvar orifice for obstetrical purposes). The Panel includes in this generic type of device those devices identified as "direct contact perineal heaters" and "noncontact radiant perineal heaters."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that perineal heaters be classified into class II (performance standards) because the Panel believes that design standards are necessary to incorporate fail-safe mechanism and a timer to control the thermal emission of the heater which, by excessive temperature or overexposure, could burn the perineal surface (pelvic floor). The Panel believes that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel also recommends that electrical safety standards be required to minimize the hazards of electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and experience with, these heaters. These devices have been in use for a long time. The device hazards and performance characteristics are well understood.

5. Risks to health: (a) Burns: Poor design or incorrect application of the device could result in tissue burns. (b) Electrical shock:

Malfunction of the device could result in electrical shock to the patient. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that perineal heaters be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5390 as follows:

§ 884.5390 Perineal heater.

(a) *Identification.* A perineal heater is a device designed to apply heat directly by contact, or indirectly from a radiant source, to the surface of the perineum (the area between the vulva and the anus) and is used to soothe or to help heal the perineum after an episiotomy (incision of the vulvar orifice for obstetrical purposes).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1167]

[FR Doc. 79–9470 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Menstrual Cups

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying menstrual cups into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of menstrual cups:

1. Identification: A menstrual cup is a receptacle placed in the vagina to collect menstrual flow.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary for reasons for recommendation: The Panel recommends that menstrual cups be classified into class II (performance standards) because the Panel believes that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel believes that standards are necessary to assure that the device is readily cleanable to prevent the introduction of microorganisms which could cause infection. The Panel also believes that material standards are necessary to assure an adequate surface finish to prevent trauma. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of, and clinical experience with, menstrual cups.

5. Risks to health: (a) Infection: If the device is not properly cleaned, it may introduce microorganisms that could cause infection. (b) Trauma, hemorrhage, perforation: Failure of the support structure of the device could result in injury to the patient. (c) Adverse tissue reaction: Material in the device could cause a local tissue or systemic reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that menstrual cups be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5400 as follows:

§ 884.5400 Menstrual cup.

(a) *Identification.* A menstrual cup is a receptacle placed in the vagina to collect menstrual flow.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may

submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N-1168]

[FR Doc. 79-9471 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Scented Deodorized Menstrual Pads

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying scented deodorized menstrual pads into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classifeed into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of scented deodorized mentrual pads:

1. Identification: A scented deodorized menstrual pad is an obsorbent cotton or synthetic material pad with fragrant chemicals added for the purpose of deodorizing or for esthetic purposes. The device is used to absorb menstrual or other vaginal discharge. This generic type of device does not include devices with added drugs or antimicrobial agents.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that scented deodorized menstrual pads be classified into class II (performance standards) because the Panel believes that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel believes that general controls alone will not provide sufficient control over this characteristic. The Panel also recommends that the caution, "Discontinue use of sensitivity or irritation occurs" be stated in the device labeling and be prominently displayed on the front of the package. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on clinical experience with these pads. The Panel reviewed the complaint file of the only manufacturer of this device at the time of its meeting (November 23, 1976). The complaints dealt with irritation associated with the cosmetic used for deodorizing.

5. Risks to health: Adverse tissue reaction: Materials in the device could cause a systemic of local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that scented deodorized menstrual pads be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safey and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5425 as follows:

§ 884.5425 Scented deodorized menstrual pad.

(a) *Identification.* A scented deodorized menstrual pad is an absorbent cotton or synthetic material pad with fragrant chemicals added for the purpose of deordorizing. The device is used to absorb menstrual or other vaginal discharge. This generic type of device does not include devices with added drugs or antimicrobial agents.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N-1169]

[FR Doc. 79-9472 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Untreated Menstrual Pads

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying untreated menstrual pads into class I (general controls). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs

proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of untreated menstrual pads:

1. Identification: An untreated menstrual pad is an absorbent cotton or synthetic material pad that is used to absorb menstrual or other vaginal discharge and that has not been treated with scent or added drugs or antimicrobial agents.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that untreated menstrual pads be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device. This simple device presents no risk to health, and the user can easily determine, by examination, whether the device is effective.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on clinical experience with these pads. The device has been in use for many years.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that untreated menstrual pad be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5435 as follows:

§ 884.5435 Untreated menstrual pad.

(a) *Identification.* An untreated menstrual pad is an absorbent cotton or synthetic material pad that is used to absorb menstrual or other vaginal discharge and that has not been treated with scent or added drugs or antimicrobial agents.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1170]

[FR Doc. 79–9473 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Scented Deodorized Menstrual Tampons

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying scented deodorized menstrual tampons into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of scented deodorized menstrual tampons:

1. Identification: A scented deodorized menstrual tampon is an absorbent cotton or synthetic material plug, inserted into the vagina, that is used to absorb menstrual or other vaginal discharge. It has fragrant chemicals added for the purpose of deodorizing or for esthetic purposes. This generic type of device does not include devices with added drug or antimicrobial agents.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation. The Panel recommends that Scented deodorized menstrual tampons be classified into class II (performance standards) because the Panel believes that the device materials should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel believes that material standards are necessary to control material absorbency and the wet strength of the removal string. Breakage of the removal string may cause difficulty in removing the tampon from the vagina. The Panel notes that excessive tampon swelling can cause pressure necrosis. At one Panel meeting, a Panel member described difficulty in removing tampons from vaginas of virginal teenagers. The Panel also recommends that the labeling specify the proper size of tampons for young girls and that the following caution be prominently displayed on the front of the package: "Discontinue Use If Sensitivity Or Irritation Occurs." The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is

sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on clinical experience with scented tampons. The Panel members related their experience with this device in several Panel meetings. There have been few adverse reports concerning these tampons.

5. Risks to health: (a) Infection: The device may increase the chance of infection or cause vaginitis or cervicitis if the device is left in place over a long period of time. (b) Adverse tissue reaction: Material or substances in the device could cause a local tissue or systemic reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that scented deodorized menstrual tampons be classified into class II (performance standards). The Commmissioner has reviewed the panel recommendation and has obtained additional data and information describing the use of scented deodorized menstrual tampons. Reports show that chronic use of tampons (whether scented or not) has caused vaginal ulcers (Ref. 1). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Barrett, K. F., S. Bledsoe, B. E. Greer, and W. Droegemueller, "Tampon-Induced Vaginal or Cervical Ulceration," *American Journal of Obstetrics and Gynecology*, 127: 332–333, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5250 as follows:

§ 884.5460 Scented deodorized menstrual tampon.

(a) *Identification.* A scented deodorized menstrual tampon is an absorbent cotton or synthetic material plug, inserted in the vagina, that is used to absorb menstrual or other vaginal discharge. It has fragrant chemicals added for the purpose of deodorizing or for esthetic purposes. This generic type of device does not include devices with added drug or antimicrobial agents.

(b) *Classification.* Class II (performance standards).

Intersted persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1171]

[FR Doc. 79–9474 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Untreated Menstrual Tampons

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying untreated menstrual tampons into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of untreated menstrual tampons:

1. Identification: An untreated menstrual tampon is an absorbent cotton or synthetic material plug that is used to absorb menstrual or other vaginal discharge and that has not been treated with scent or added drugs or antimicrobial agents.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that untreated menstrual tampons be classified into class II (performance standards) because the Panel believes that device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel believes that material standards are necessary to control material absorbency and the wet strength of the removal string to prevent difficulty due to breakage of the tampon plug or removal string when removing the tampon from the vagina. The Panel notes that tampon swelling can cause pressure necrosis. At one Panel meeting, a Panel member described difficulty in removing tampons from the vaginas to provide sufficient control over these characteristics. The Panel also recommends that the labeling specify the proper size of tampons for young girls. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on clinical experience with these tampons. The untreated tampon has been on the market for a long time with minimal adverse reports.

5. Risks to health: (a) Infection: If the device is not properly sterilized, it may introduce microorganisms that could cause infection. (b) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that untreated menstrual tampons be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation and has obtained other data and information. Reports show that chronic use of tampons has caused vaginal ulcers (Ref. 1). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Barrett, K. F., S. Bledsoe, B. E. Greer, and W. Droegemueller, "Tampon-Induced Vaginal or Cervical Ulceration," *American Journal of Obstetrics and Gynecology*, 127:332–333, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540—546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5470 as follows:

§ 884.5470 Untreated menstrual tampon.

(a) *Identification.* An untreated menstrual tampon is an absorpbent cotton or synthetic material plug that is used to absorb menstrual or other vaginal discharge and that has not been treated with scent or added drugs or antimicrobial agents.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1172]

[FR Doc. 79–9475 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Vaginal Douche Kits

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vaginal douche kits into class II (Performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of vaginal douche kits:

1. Identification: A vaginal douche kit consists of a bag or a bottle with a nozzle designed to direct a stream of water or solution into the vaginal cavity to cleanse the vagina. The device is not for contraception. A douche kit that includes chemicals or solutions is an over-the-counter vaginal drug product.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that vaginal douche kits be classified into class II (performance standards) because the Panel believes that design standards are necessary to assure that the jet-spray pressure does not force the cleansing solution into the uterus and peritoneal cavity. The Panel believes that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also recommends that the nozzle be cleaned properly to prevent infection and that the device not be used during pregnancy, nor in the first 6 weeks after abortion or childbirth. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on extensive experience with the douche kit, and information from the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Productrs, another FOA advisory committee. Case reports of salpingitis (fallopian tube inflammation) and peritonitis produced by vaginal douche fluid under pressure have been related to the use of douche kits. The Panel members also reviewed the literature on the device (Refs. 1 through 5). These articles suggest that douching is essentially a safe modality, and it can serve as a useful adjunct to treatment of certain conditions.

5. Risks to health: (a) Infection: If the device is not properly cleaned, it may introduce microorganisms that could cause infection. (b) Trauma or perforation: Improper structure of the device could result in injury to the patient. (c) Peritonitis: (inflammation of the peritoneal cavity). Excessive pressure could result in the solution in the douche entering the uterus and the peritoneal cavity. This could lead in peritonitis.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that vaginal douche kits be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendations and has obtained other data and information describing the use of the vaginal douche kit. Peritonitis may also be caused by prolonged use of a suspension of powder in water as a douche solution

(Ref. 6). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Barnes, J., "Uses and Abuses of Vaginal Douching," *Practitioner*, 184:668, 1960.

2. Glynn, R., "Vaginal pH and the Effect of Douching," *Obstetrics and Gynecology*. 20:369–372, 1962.

3. Glynn, R., "Daily Douching: Effect on Vaginal Mucosa," *Obstetrics and Gynecology*, 22:640–642, 1963.

4. Karnaky, K. J., "Normal Physiologic Vaginal Douches," *American Journal of Surgery*, 101:458–462, 1961.

5. Neumann, H. H., A. DeCherney, "Douching and Pelvic Inflammatory Disease." *New England Journal of Medicine*, 295:789, 1976.

6. Hidvegi, D., I. Hidvegi, and J. Barnett, "Douche-Induced Pelvic Peritoneal Starch Granuloma," *Obstetrics and Gynecology*. 52(1) (Supplement): 15S–18S, July 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5900 as follows:

§ 884.5900 Vaginal douche kit.

(a) *Identification.* A vaginal douche kit is a device used to direct a stream of water or solution into the vaginal cavity to cleanse the vagina. The device is not for contraception. A douche kit that includes chemicals or solution is an over-the-counter vaginal drug product.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs

[Docket No. 78N–1173]

[FR Doc. 79–9476 Filed 4–2–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 884]

Classification of Vaginal Insufflators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vaginal insufflators into class I (general controls). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of vaginal insufflators:

1. Identification: A vaginal insufflator is a device used to treat vaginitis by introducing medicated powder from a hand-held bulb into the vagina through an open speculum.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that vaginal insufflators be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This simple device presents no risk to health, and the user can easily determine whether the device is effective. The Panel also recommends that this device be used by a professional and only when the vagina is held open with a speculum (Ref. 1).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on knowledge of and clinical experience with this device. This device has been widely used for many years (Ref. 1).

5. Risks to health: The Panel identified no risks to health.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that viginal insufflators be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Kimbrough R., "Gynecology," J. B. Lippincott Co., Philadelphia, PA, p. 267, 1965.

Therefore, under the Federal Food, Drug, and Cosemtic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5920 as follows:

§ 884.5920 Vaginal insufflator.

(a) *Identification.* A vaginal insufflatory is a device used to treat vaginitis by introducing medicated powder from a hand-held bulb into the vagina through an open speculum.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 4, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may

submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N-1174]

[FR Doc. 79-9477 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Powered Vaginal Muscle Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered vaginal muscle stimulators into class III (premarket approval). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. In a future issue of the **Federal Register,** the agency will publish the recommendation of the Gastroenterology and Urology Device Classification Panel, is making recommendations with respect to the classification of the powered vaginal muscle stimulators used for treating urinary incontinence. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the folowing recommendation with respect to the classification of powered vaginal muscle stimulators for treatment of sexual dysfunction:

1. Identification: A powered vaginal muscle stimulator is an electrically powered device designed to stumilate directly the muscles of the vagina with pulsating electrical current. This device is used to increase musclular tone and strength in the treatment of sexual dysfunction. This generic type of device does not include devices used to treat urinary incontinence.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the powered vaginal muscle stimulator be classified into class III because the Panel believes that satisfactory performance has never been demonstrated. The Panel questions the usefulness of this device when used in the treatment of sexual dysfunction. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the device. The Panel found no data available concerning the effectiveness of this device for treating sexual dysfunction.

5. Risks to health: (a) Burns: Improper voltage control of the device could result in electrical burns when the device comes in contact with vaginal tissue. (b) Electrical shock: Malfunction of the device could result in electrical shock to the patient. (c) Irritation, truama, hemorrhage, and perforation: Improper shape, or other design shortcomings, of the device could cause injury to vaginal tissue. (d) Adverse tissue reaction: Material or substances in the device could cause a local tissue or systemic reaction when the device comes into contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that powered vaginal muscle stimulators be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and has obtained additional data and information describing the application of the powered vaginal muscle stimulator. This device has fallen into disuse in sex therapy (Ref. 1), and the published data are not adequate to demonstrate the safety and effectiveness of the device. The Commissioner believes that the device is purported or represented to be for a use (treatment of sexual dysfunction) that is of substantial importance in preventing impairment of human health. The Commissioner believes that the device presents a potential unreasonable risk of illness or injury because its effectiveness has never been documented, and it presents serious risks to health. The Commissioner also believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Oliver, J. F. "Clinical Sexuality," 3d Ed., J. B. Lippincott Co., Philadelphia, p. 418, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5940 as follows:

§ 884.5940 Powered vaginal muscle stimulator.

(a) *Identification.* A powered vaginal muscle stimulator is an electrically powered device designed to stimulate directly the muscles of the vagina with pulsating electrical current. This device is used to increase muscular tone and strength in the treatment of sexual dysfunction. This generic type of device does not include devices used to treat urinary incontinence.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and

shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory affairs.

[Docket No 78N-1175]

[FR Doc. 79-9478 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Genital Vibrators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying genital vibrators into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of genital vibrators:

1. Identification: A genital vibrator is an electrically operated device used to vibrate the female genitals as a form of massage in the treatment of sexual dysfunction and as an adjunct to Kegel's exercise (tightening of the muscles of the pelvic floor, to increase muscle tone).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that genital vibrators be classified into class II (performance standards) because the Panel believes that electrical safety standards are required to minimize the hazards of electrical shock or burn to genital tissues. The Panel also believes that the device materials contacting genital tissues should meet a biocompatibility standard to prevent adverse tissue reaction. The hazard of vaginal, urethral, vulvar, or rectal laceration can be controlled by a material standard which will assure adequate surface finish and by a design standard which will assure appropriate shape of the device. The Panel recommends that proper instructions against misuse be stated in the device labeling. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on their personal knowledge of, and clinical experience with, genital vibrators. Panel member Dr. John Josimovich contacted and polled 10 chairmen of medical centers and obstetrics-gynecology departments across the nation and one major sexual dysfunction specialist. Dr. Josivomich failed to discover a single hospital admission or an office visit for vaginal or vulvar lacerations caused by use of a genital vibrator. The Panel members also reviewed articles on the device in popular publications (Refs. 1 and 2).

5. Risks to health: (a) Burns: Poor design or incorrect application of the device could result in tissue burns if the device heats the patient's tissue by friction. (b) Laceration and abrasion: Improper shape and/or roughness of the device could cause patient injury. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient. (d) Electrical shock: Malfunction of the device could result in electrical shock to the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that genital vibrators be classified into class II (performance standards). The Commissioner has reviewed the Panel recommendation and has obtained other data and information describing the use of genital vibrators as an adjunct to Kegel's exercises (Ref. 3). Kegel's exercises are prescribed to increase the strength and tone of the pelvic muscles in the treatment of genital relaxation, urinary stress incontinence, and sexual dysfunction (Ref. 4). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Barbach, L. G., "For Yourself," Doubleday & Co., Inc., Garden City, NY, pp. 106-107, 1975.

2. Murray, L., "Vibrators: Everything you must know—How do men feel about them? Can they harm you? Are they habit forming?" *Playgirl*, pp. 80-83, December 1975.

3. Oliven, J. F., *Clinical Sexuality: A Manual for the Physician and the Professions*, 3d Ed., J. B. Lippincott Company, Philadelphia, pp. 197, 418-419, 1974.

4. Kegel, A. H., "Exercise in the Treatment of Genital Relaxation, Urinary Stress Incontinence, and Sexual Dysfunction," *in* "Office Gynecology," 9th Ed., Edited by Greenhill, J. P., Year Book Medical Publishers Inc., Chicago, pp. 188-200, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5960 as follows:

§ 884.5960 Genital vibrator.

(a) *Identification.* A genital vibrator is an electrically operated device used to vibrate the vagina as a form of massage in the treatment of sexual dysfunction, and as an adjunct to Kegel's exercise (tightening of the muscles of the pelvic floor, to increase muscle tone).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers lane, Rockville, MD 20857, written comments regarding this proposal. Four

copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N-1176]

[FR Doc. 79-0479 Filed 4-2-79; 8:45 am]

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